

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

DIRECT MARKETING CONCEPTS, INC., et
al.,

Defendants.

CIVIL ACTION NO. 04-CV-11136-GAO

**DEFENDANTS DIRECT MARKETING CONCEPTS, INC.,
ITV DIRECT, INC., DONALD BARRETT AND ROBERT
MAIHOS' STATEMENT OF MATERIAL FACTS IN DISPUTE**

Defendants Direct Marketing Concepts, Inc., ITV Direct, Inc., Donald Barrett and Robert Maihos (the “DMC Defendants”), pursuant to Local Rule 56.1, submit the following statement of material facts as to which there exists a genuine issue to be tried.¹ Reviewing the Federal Trade Commission’s (“FTC”) statement of facts, it is clear that numerous issues of disputed facts exist in this case, which cannot be resolved on a motion for summary judgment. Much of the FTC’s evidence is simply its interpretation of certain documents and testimony, with no regard for directly contrary documents or statements by other witnesses. These disputes of fact are not trivial or irrelevant, but go to the heart of the claims asserted by the FTC, mandating a trial of this action. The specific assertions of fact that are disputed by the DMC Defendants are set forth below:

¹ Given the length of the FTC’s submission, and to ease the Court’s ability to cross reference the documents, the DMC Defendants have set forth their statement of disputed facts by reference to the corresponding paragraphs in the FTC’s statement. In addition, because much of the disputed evidence is already in the record or is contained in documents submitted by the FTC, the DMC Defendants have not resubmitted these affidavits or exhibits, which are referenced either as “Docket No. __” or “FTC Summary Judgment Exhibit __”.

1. The FTC states that it is an agency of the United States Government created by the FTC Act. As an agency of the United States Government, the FTC's powers are limited by the First and Fifth Amendments to the United States Constitution, as well as by the Administrative Procedure Act. As such, the FTC's restrictions on commercial speech are subject to judicial review and may not be arbitrary and capricious. *See* Complaint, *Direct Marketing Concepts, Inc. v. FTC*, Case No. 05-11930 GAO (D. Mass.), filed September 23, 2005, attached as Exhibit 1 to Affidavit of Christopher F. Robertson ("Robertson Aff."), filed herewith; *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

2. The FTC states that on June 1, 2004 it filed the present action, naming a number of parties as defendants. The FTC, however, did not name Kevin Trudeau or Robert Barefoot as defendants in this case. Despite Mr. Trudeau's and Mr. Barefoot's significant and central roles in the coral calcium infomercial, the FTC did not name either of them as parties in this case because the FTC had already filed suit against them in another jurisdiction over a year earlier. *See* Complaint, *FTC v. Trudeau, et al.*, Civ. Act. No. 03 C 3904 (N.D. Ill.), originally filed on June 4, 2003, attached as Exhibit 2 to Robertson Aff. The FTC then waited over a year to make any claims concerning the coral calcium infomercial against the present defendants, despite the fact that the coral calcium infomercial had not aired since May 2003, and had been taken off the air by Direct Marketing Concepts immediately upon request by the FTC. Despite being previously enjoined by the FTC, and despite the fact that Mr. Trudeau's sales of coral calcium exceeded \$120 million, the FTC settled its claims against Mr. Trudeau in 2004 for \$2 million, and settled with Mr. Barefoot for no monetary payment. *See* Stipulated Final Order For Permanent Injunction and Settlement of Claims for Monetary Relief as to Defendants Robert Barefoot, Deonna Enterprises, Inc. and Karbo Enterprises, Inc., *FTC v. Trudeau, et al.*, Civ. Act.

No. 03 C 3904 (January 6, 2004), Robertson Aff., Ex. 3; Stipulated Final Order For Permanent Injunction and Settlement of Claims for Monetary Relief as to Defendants Kevin Trudeau, et al., *FTC v. Trudeau, et al.*, Civ. Act. No. 03 C 3904 (September 4, 2004), Robertson Aff., Ex. 4; Responses to Interrogatories Submitted by Kevin Trudeau, Robertson Aff., Ex. 19.

3. On April 20, 2005, the FTC amended its Complaint in this action to add additional parties, including Defendant Robert Maihos. *See* Docket No. 67. In doing so, however, the FTC failed to allege that Mr. Maihos had any direct involvement in the production or content of any of the subject advertising. *Id.*

4. On September 28, 2005, the FTC settled its claims with defendant Alejandro Guerrero. *See* Docket No. 114. Despite Mr. Guerrero's central role in the Supreme Greens advertising, the FTC settled with Mr. Guerrero for a total payment of \$65,000, or the relinquishment of his automobile. *Id.*

5. In September 2005, the FTC settled its claims with defendants Michael Howell and Gregory Geremesz. *See* Docket No. 116. Despite their significant role in the conduct alleged by the FTC, the FTC settled with these defendants for a total combined payment of \$15,000. *Id.*

6. In May 2005, the FTC sought to appoint a receiver in this case for the second time, after that relief was initially denied by this Court. *See* Docket No. 68. The FTC's basis for seeking a receiver was premised on advertising that it had not previously challenged in any administrative or legal forum. *See* Docket No. 70. Moreover, in opposing the FTC's motion related to this new advertising, the DMC Defendants provided massive amounts of scientific evidence and support, as well as a number of affidavits from scientific experts. *See* Docket No. 75 (Affidavit of Frank Greenway, M.D.), Docket No. 76 (Affidavit of Christine A. Maggs,

Ph.D.), Docket No. 77 (Declaration of Ronlad J. Amen, Ph.D.), Docket No. 78 (Declaration of Larry Haase), Docket No. 91 (Affidavit of Jane Teas, Ph.D.), Docket No. 121 (Affidavit of David Myslabodski, Ph.D.), Docket No. 122 (Affidavit of Stephan Kraan, Ph.D.). In addition, in September 2005, the DMC Defendants filed suit against the FTC, alleging that the FTC's actions violated the First and Fifth Amendments to the United States Constitution, and the Administrative Procedure Act. *See* Robertson Aff., Ex. 1. The FTC has moved to dismiss that complaint on subject matter jurisdiction grounds, claiming that the issues are not ripe and/or the DMC Defendants lack standing to raise these claims. *See* Docket No. 4, *Direct Marketing Concepts, Inc. v. FTC*, Case No. 05-11930 GAO (D. Mass.). The DMC Defendants disagree and have opposed the FTC's motion. *Id.* The arguments contained in the DMC Defendants' opposition to that motion are incorporated herein.

7. Defendant Direct Marketing Concepts ("DMC") is a Massachusetts corporation with its principal place of business at 55 Cherry Hill Drive, Beverly, Massachusetts. *See* Robertson Aff., Ex. 1, ¶ 2. DMC's business includes the production of infomercials, in which an individual or company is provided with an opportunity to advertise an existing product to a larger audience through television, radio and other media outlets. *See* Affidavit of Donald Barrett, dated June 4, 2004 ("Barrett Aff., 6/4/04"), located at Docket No. 9, with accompanying exhibits separately filed with Clerk's Office, Docket No. 10. DMC currently employs over 350 Massachusetts residents. *See* Supplemental Affidavit of Donald Barrett, dated February 10, 2006 ("Barrett Aff., 2/10/06"); Affidavit of Jason Bernabei, dated January 25, 2006 ("Bernabei Aff., 1/25/06").

8. DMC was incorporated in Massachusetts in June 2001. At that time, DMC's sole business was answering the telephones in connection with direct response advertising produced

and distributed by other individuals or companies. During 2001, DMC began to seek out its own potential products that might be benefited by direct response advertising. DMC, however, had no independent capacity to produce or edit its own advertising. Rather, DMC hired other individuals or companies to produce and edit advertising. Alternatively, DMC sought to obtain distribution rights to existing infomercials. Likewise, in 2001 DMC had no capacity to purchase products or receive funds from consumers. All of these activities were conducted by other entities with which DMC had contractual agreements. *See* Deposition of Donald Barrett, December 22, 2003 (“Barrett Depo., 12/22/03”) at pp. 20-35, 52, FTC Summary Judgment Exhibit 6; Barrett Aff., 6/4/04, Docket No. 9, at ¶¶ 5, 7; Barrett Depo., 7/21/05, at pp. 26-27, FTC Summary Judgment Exhibit 7; Barrett Depo., 3/25/02, at pp. 11-14, Robertson Aff., Ex. 6; Stern Depo., 1/14/03, pp. 10-11, Robertson Aff., Ex. 8; Stern Depo., 7/15/05, at p. 28, FTC Summary Judgment Exhibit 15.

9. Because of DMC’s limited operations and capacity, all activities in connection with the coral calcium infomercial, with the exception of answering the telephones and conveying customer orders to others for processing, were handled by other individuals and entities until March 2003. For a brief period, lasting only two months, DMC did purchase a limited amount of media, process some customer orders and sell some coral calcium products. These sales represented a small fraction of the total sales of the product through the infomercial, the vast majority of which were processed through Triad ML Marketing and King Media from 2001 through March 2003. *See* Barrett Depo., 12/22/03, at p. 52, FTC Summary Judgment Exhibit 6; Barrett Aff., 6/4/04, Docket No. 9, at ¶ 7; Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Stern Depo., 1/14/03, pp. 10-11, 27, Robertson Aff., Ex. 8; Stern

Depo., 3/25/02, pp. 12-17, Robertson Aff., Ex. 7; Stern Depo., 7/15/05, at pp. 28-30, 40, FTC Summary Judgment Exhibit 15.

10. In November 2001, Donald Barrett asked Kevin Trudeau, a popular figure in the infomercial industry, whether he would be interested in producing a show relating to the product coral calcium. After receiving a favorable response from Mr. Trudeau, Mr. Barrett arranged to have Mr. Barefoot meet with Mr. Trudeau to film the show. All studio time was arranged by Mr. Trudeau and all editing of the show was undertaken by Mr. Trudeau. All media for the show until March 2003 was purchased by Allen Stern and King Media and all customer orders were processed by Allen Stern and Triad ML Marketing. While DMC has sold the product Coral Calcium Daily, coral calcium products are widely sold and distributed by many companies in the United States and abroad and coral calcium is an common dietary supplement. DMC only sold Coral Calcium Daily through the infomercial for a very brief period in 2003 before the show was permanently pulled from the air. *See* Barrett Depo., 12/22/03, at p. 52, FTC Summary Judgment Exhibit 6; Barrett Aff., 6/4/04, Docket No. 9, at ¶ 7; Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Stern Depo., 3/25/02, pp. 12-17, Robertson Aff., Ex. 7; Stern Depo., 1/14/03, pp. 10-11, 27, Robertson Aff., Ex. 8; Stern Depo., 7/15/05 at pp. 28-30, 154, FTC Summary Judgment Exhibit 15.

11. From 2001 through March 2003, all media decisions regarding where and when the coral calcium infomercial would air were made by Allen Stern and King Media. DMC had no control over the airing of the infomercial. Moreover, the infomercial did not discuss any particular product. Rather, the infomercial simply discussed Mr. Barefoot's previously published books and studies on the benefits of coral calcium generally to health and well being. At no time did the infomercial identify a specific brand of coral calcium or identify Coral Calcium Daily.

See Barrett Depo., 12/22/03, at pp. 20-35, 52, FTC Summary Judgment Exhibit 6; Barrett Aff., 6/4/04, Docket No. 9, at ¶¶ 5, 7; Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Barrett Depo., 3/25/02, at pp. 11-14, Robertson Aff., Ex 6; Stern Depo., 1/14/03, pp. 10-11, 27, Robertson Aff., Ex. 8; Stern Depo., 7/15/05, at pp. 28, 30, 40, FTC Summary Judgment Exhibit 15.

12. ITV Direct, Inc. (“ITV”) is a Massachusetts corporation with its principal place of business at 55 Cherry Hill Drive, Beverly, Massachusetts. ITV and DMC are separate companies. ITV was established as primarily a media purchasing company, to purchase media time for other companies including DMC, similar to the functions that had previously been performed by Allen Stern and King Media. *See* Affidavit of Wayne Callahan, dated January 26, 2006 (“Callahan Aff., 1/26/06”); Barrett Aff., 2/10/06.

13. ITV was incorporated in Massachusetts in January 2003. However, ITV did not engage in any activities for several months, until April 2003, when it entered into a contractual agreement with the Healthy Solutions defendants. *See* Barrett Aff., 2/10/06.

14. In connection with its relationship with the Healthy Solutions defendants, ITV purchased media time for the Supreme Greens infomercial. However, customer orders were received by DMC and all customer fulfillment was handled by companies other than ITV. *See* ITV Direct, Inc.’s Answer to Interrogatories, Ans. No. 3, 4, January 21, 2005, Robertson Aff., Ex. 15.

15. ITV entered into a distribution agreement with Healthy Solutions to market and distribute Supreme Greens with MSM, a product that had been previously developed, advertised and sold by defendant Guerrero. The distribution agreement provided that Guerrero would be responsible for all claims made concerning the product and would indemnify and hold ITV

harmless in connection with any such claims. *See* Barrett Depo., 7/21/05, Attachment 10, FTC Summary Judgment Exhibit 7; Geremesz Depo., at pp. 85-86, Robertson Aff., Ex. 18; Guerrero Depo., Attachment 6, Robertson Aff., Ex. 19.

16. After the infomercial was produced, a copy was provided to Guerrero for his review before it was aired. Guerrero was asked to confirm that he had substantiation for all of his statements in the infomercial, and that he was comfortable with the content of the infomercial. Guerrero confirmed to ITV that he did have substantiation for all of his claims, and stated that such substantiation would be provided to ITV. Based upon these representations, among others, ITV began purchasing media time for the show and allowed it to air. *See* Bernabei Aff., 1/25/06; Barrett Depo., 7/21/05, at pp. 91, 100-102, FTC Summary Judgment Exhibit 7; Affidavit of Eileen Barrett Maihos, dated January 26, 2006 (“E. Barrett Maihos Aff., 1/26/06).

18. Barrett is the President and a director of both DMC and ITV. Since founding DMC in 2001, Barrett has grown the business from a few employees to over 350 employees. Barrett has also hired a full-time in-house attorney to review all shows, scripts, contracts and other communications, and has hired a scientific adviser to review substantiation for all shows aired by DMC or ITV. Barrett has also grown the companies’ customer service departments and sales training resources, to assure that all customers of these companies are given the highest level of service and are satisfied with their customer experience. From the first day of operations it has always been DMC’s policy to provide a customer with the opportunity to return product for a full refund for any reason. *See* Barrett Aff., 6/7/05, Docket No. 80, at ¶ 18; Affidavit of Catherine Ratcliff, dated June 7, 2005 (“Ratcliff Aff., 6/7/05”), Docket No. 85, at ¶¶ 11,13; Barrett Depo., 7/21/05, at p. 203, FTC Summary Judgment Exhibit 7; Barrett Aff., 2/10/06.

19. While DMC and ITV currently engage in a full service operation, including purchasing media, answering telephones, customer service and order fulfillment, DMC and ITV did not have this capacity until 2003, after the coral calcium program was no longer airing to the public. Prior to that time, as recognized by the FTC, all media purchases, customer fulfillment and receipt of customer funds was undertaken and controlled by Triad and King Media, companies entirely unrelated to DMC, ITV or Barrett. *See* Barrett Depo., 12/22/03, at pp. 20-35, 52, FTC Summary Judgment Exhibit 6; Barrett Aff., 6/4/04, Docket No. 9, at ¶ 7; Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Barrett Depo., 3/25/02, at pp. 11-14, Robertson Aff., Ex. 6; Stern Depo., 1/14/03, pp. 10-11, 27, Robertson Aff., Ex. 8; Stern Depo., 7/15/05, at pp. 28, 30, 40, FTC Summary Judgment Exhibit 15; Ritchey Depo., 2/13/03, Robertson Aff., Ex. 26.

20. As with many consumer product companies, DMC and ITV sell to distributors. These distributors are independent companies that are not under the ownership or control of DMC or ITV, have their own management, and have no obligation to buy any products from DMC or ITV. Nonetheless, DMC and ITV do attempt to monitor the activities of its distributors to determine if their actions may be detrimental to DMC's or ITV's business. If a distributor is engaging in inappropriate conduct in connection with its sales of products, DMC and ITV may take action against that distributor, including refusing to engage in further transactions. *See* Affidavit of Michael Sciucco, dated September 28, 2005 ("Sciucco Aff., 9/28/05"), Docket No. 120, at ¶ 33; Bernabei Aff., 1/25/06; Stern Depo., 7/15/05, at p. 158, FTC Summary Judgment Exhibit 15.

21. While Barrett testified that there is some overlap between ITV and DMC, they are separate companies incorporated at separate times. Each company maintains its own accounting

systems, general ledger, and bank accounts. Each company also files its own tax returns. *See* Callahan Aff., 1/26/06; Barrett Aff., 2/10/06.

22. Direct Fulfillment is an entirely separate company that is not owned by either Barrett or Maihos, but is owned by a third party unrelated to either DMC or ITV. *See* Callahan Aff., 1/26/06.

23. Although “Today’s Health” was a moniker utilized by Barrett in connection with certain advertising, that name was not utilized in connection with the coral calcium or Supreme Greens infomercials. *See* Barrett Depo., 12/22/03, p. 15, FTC Summary Judgment Exhibit 6.

26. All advertising produced by DMC or ITV is currently reviewed by in-house counsel and the company’s scientific adviser before it is disseminated to the public. *See* Barrett Aff., 2/10/06; Affidavit of Andrew Aldrich, dated February 9, 2006 (“Aldrich Aff., 2/9/06”). This advertising is also often reviewed by outside counsel and outside advisers. All advertising is also reviewed by the participants for content. These procedures have been in place at DMC and ITV since 2004. *See* Sciucco Aff., 6/6/05, Docket No. 86. Moreover, in connection with the coral calcium infomercial produced by Kevin Trudeau, Barrett relied upon Trudeau and Stern to edit and review the infomercial for compliance with all applicable laws and regulations. As part of this process, Barefoot worked closely with Trudeau’s employees to provide them substantiation and scientific support for the program. *See* Barefoot Depo. 9/11/04 at pp. 69-73, Robertson Aff., Ex. 9. Trudeau had the tape edited for final content and produced a completed “master” tape, which he then sent to Barrett. Mr. Barefoot testified that Kevin Trudeau was responsible for editing the infomercial and that Mr. Trudeau would have the infomercial reviewed by FTC experts. Barefoot additionally testified that he provided Trudeau’s people with substantiation for all of his claims. *See* Barefoot Depo., 9/11/04 at pp. 69-73, Robertson Aff.,

Ex. 9. Both Trudeau and Stern told Barrett that they had submitted the infomercial to experts, including lawyers, for review and that the tape was proper to air. *See* Stern Depo., 7/15/05 at pp. 73, 75, FTC Summary Judgment Exhibit 15; Ritchey Depo., 7/14/05, at p. 149, FTC Summary Judgment Exhibit 16. Stern also testified that his employee, Susan Graham, compiled “several hundred” pages of articles and research. Stern Depo., 7/15/05, at p. 67, FTC Summary Judgment Exhibit 15. Barrett relied on these representations in connection with the infomercial. Likewise, Barrett relied upon Guerrero’s final review and approval of the Supreme Greens tape before airing it to the public. *See* Bernabei Aff., 1/25/06; Barrett Depo., 12/22/03, at pp. 43, 46, 49-52, FTC Summary Judgment Exhibit 6; Barrett Aff., 2/10/06.

27. The DMC Defendants dispute the FTC’s evidence regarding the DMC Defendants’ marketing materials. As with DMC’s and ITV’s advertising, all brochures and packaging inserts are currently reviewed by counsel before they are disseminated to the public. *See* Sciucco Aff., 6/6/05, Docket No. 86. In connection with the coral calcium infomercial, all of the content of the marketing materials and brochures was derived from the materials published and widely disseminated by Robert Barefoot. *See* Limbaugh Depo., 5/16/05 at p. 241, FTC Summary Judgment Exhibit 10. As a well-known author of books on coral calcium who had appeared regularly on local and national media, Barefoot’s claims about the benefits of coral calcium were widely available. *See* Barefoot Depo., 9/11/04, at pp. 15, 17, 22, Robertson Aff., Ex. 9. Moreover, these materials were produced and edited by Allen Stern and Triad, who had the relationships with the printing companies and sent all product to customers. *See* Maihos Depo., 4/7/05, at pp. 37-38, FTC Summary Judgment Exhibit 9; Ritchey Depo., 7/14/05, at pp. 174-175, FTC Summary Judgment Exhibit 16; Barrett Aff., 2/10/06, Exhibit 1; Stern Depo., 3/25/02, at p. 9, Robertson Aff., Ex. 7; Affidavit of Susan Graham, dated February 21, 2003,

Robertson Aff., Ex. 25. In connection with the Supreme Greens advertising, all statements in any marketing materials were consistent with information provided by Guerrero, and neither Barrett nor ITV made any statement that exceeded information provided by Guerrero. Guerrero reviewed these materials regularly and had the ultimate power to reject any statement that he believed was not justified or substantiated. At no time did he reject any statements in any of these materials. *See* Barrett Depo., 7/21/05, (Attachment 3, meeting minutes from September 9, 2003, Bates No. DMC 041350), FTC Summary Judgment Exhibit 7. *See also* Limbaugh Depo., 5/16/05 at pp. 21, 32, 217, FTC Summary Judgment Exhibit 10; Affidavit of Simon Mena, January 25, 2006 (“Mena Aff., 1/25/06”); Maihos Aff., 6/4/04, Docket No. 11, ¶¶ 4-5; Bernabei Aff., 1/25/06.

28. As with all advertising, brochures and similar materials, every sales script, power sheet or other written document available to the sales floor currently is reviewed by counsel for content before it is disseminated. *See* Sciucco Aff., 6/6/05, Docket No. 86. In connection with the coral calcium infomercial, all of the content of sales scripts was derived from the materials published and widely disseminated by Robert Barefoot. *See* Limbaugh Depo., 5/16/05 at p. 242, FTC Summary Judgment Exhibit 10. As a well-known author of books on coral calcium who had appeared regularly on local and national media, Barefoot’s claims about the benefits of coral calcium were widely available and the sales personnel were instructed that they were to limit any and all comments to customers to the content of the books. *See* Barefoot Depo., 9/11/04, at pp. 69-73, Robertson Aff., Ex. 9; Barefoot Biography, Robertson Aff., Ex. 27. With the exception of the first coral calcium script, which was drafted by Donald Barrett, these coral calcium scripts and power sheets were produced and edited by Allen Stern and Triad. *See* Maihos Depo., 4/7/05, at pp. 37-38, FTC Summary Judgment Exhibit 9; Barrett Aff., 2/10/06, Exhibit 2; Stern Depo.,

3/25/02, at p. 9, Robertson Aff., Ex. 7. In connection with the Supreme Greens advertising, all content in the sales scripts was provided by Guerrero, and the sales personnel were instructed that they were not to make any statements that deviated from the information provided by Guerrero. *See* Mena Aff., 1/25/06. Erik Limbaugh also testified that he personally called Guerrero to collect and verify the information in the materials. *See* Limbaugh Depo., 5/16/05 at p. 241, FTC Summary Judgment Exhibit 10. Guerrero met with the sales force on several occasions to provide them information to convey to customers, and he reviewed these materials regularly. *See* Maihos Aff., 6/4/04, ¶¶ 4-5, Docket No. 11 (attaching Guerrero discussion with sales force). Guerrero had the ultimate power to reject any statement that he believed was not justified or substantiated. At no time did he reject any statements in any of these materials. The DMC defendants also dispute that Barrett was involved in drafting and writing the scripts and power sheets, and Barrett directly contradicted that he had final review of those scripts during his deposition. *See* Limbaugh Depo., 5/16/05 at pp. 21, 32, 217, FTC Summary Judgment Exhibit 10; Mena Aff., 1/25/06; Barrett Depo., 7/21/05, at pp. 42, 46, 53, FTC Summary Judgment Exhibit 7.

29.-38. Defendant Robert Maihos is an officer and director of DMC and ITV, and handles operations for both companies. While Mr. Maihos has responsibility for many of the “back office” operations of DMC and ITV, he is not responsible for locating products or potential advertising, he does he have any responsibility for reviewing or editing the content of advertising or purchasing media, nor does he have responsibility for sales and marketing. *See* Maihos Depo., 6/20/05, at pp. 11, 175, FTC Summary Judgment Exhibit 8; Mena Depo., 4/8/05, at p. 41, FTC Summary Judgment Exhibit 21; Ritchey Depo., 7/14/05, at pp. 139-140, FTC

Summary Judgment Exhibit 16; Stern Depo., 7/15/05, *passim*, FTC Summary Judgment Exhibit 16 (no mention of any significant role by Maihos in coral calcium advertisement).

39.-60. In connection with the coral calcium infomercial featuring Robert Barefoot and Kevin Trudeau, Allen Stern, King Media and Triad were responsible for all aspects of the marketing and sales of Barefoot's books and coral calcium products from 2001 through March 2003. All decisions regarding the placement of media, all purchasing of books and product, and all processing and fulfillment of customer orders were provided by Triad and King Media. In addition, all merchant accounts were controlled by Triad and all customer funds were paid to Triad. *See* Barrett Depo., 12/22/03, FTC Summary Judgment Exhibit 6, (Attachment 5, Affidavit of Donald Barrett, dated March 13, 2002 ¶¶ 15-17). Other than answering the telephones and taking customer orders, DMC and Barrett had a limited role, and did not themselves directly receive any customer funds. *See* Barrett Depo., 12/22/03, at pp. 20-35, 52, FTC Summary Judgment Exhibit 6; Barrett Aff., 6/4/04, Docket No. 9, at ¶¶ 5, 7; Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Barrett Depo., 3/25/02, at pp. 11-14, Robertson Aff., Ex. 6; Stern Depo., 1/14/03, pp. 10-11, Robertson Aff., Ex. 8; Stern Depo., 7/15/05 at pp. 27-28, 30, 151, FTC Summary Judgment Exhibit 15; Ritchey Depo., 2/13/03, Robertson Aff., Ex. 26.

61.-67. BP International, Inc. is a Nevada company that is unrelated to either DMC or ITV. For a period of time prior to 2003, BP International handled some master distributor relationships in connection with the coral calcium advertising. BP International worked directly with Triad to provide distributors with coral calcium product. BP International is not owed by Barrett, nor is Barrett an officer or director of the company. *See* Barrett Depo., 7/21/05, pp. 40,

243, FTC Summary Judgment Exhibit 7; Barrett Aff., 2/10/06; Stern Depo., 7/15/05 at pp. 151-52, FTC Summary Judgment Exhibit 15.

68. Mr. Barrett did correspond with Kevin Trudeau in late 2001 concerning coral calcium. Mr. Barefoot had published two books, “The Calcium Factor” and “Death by Diet,” which expressed Mr. Barefoot’s opinion, supported by numerous citations to scientific and medical literature, that coral calcium could have tremendous health benefits. *See* Copies of “The Calcium Factor” and “Death By Diet”, attached to Robertson Aff. as Exhibits 10, 11. Mr. Barefoot also had previously spoken publicly on news and other informational programs, and had made another infomercial. *See* Barefoot Depo., 9/11/04, Robertson Aff., Ex. 9. In his correspondence, Mr. Barrett included videotapes of other coral calcium infomercials featuring Mr. Barefoot that were already airing and had been airing for some time. Thus, while Mr. Barrett believed that a show featuring Mr. Trudeau and Mr. Barefoot could be successful, he also knew that the substance of the show, including Mr. Barefoot’s claims about the benefits of coral calcium, was already in the public domain. Barrett also read Barefoot’s books, which contained citations to scientific literature, studies and other resources supporting Barefoot’s opinions in his book. *See* Barrett Depo., 12/22/03, at p. 53, FTC Summary Judgment Exhibit 6; Barrett Depo., 3/25/02, at pp. 24-30, Robertson Aff., Ex. 6; Barrett Aff., 6/4/04, Docket No. 9; Barefoot Depo., 9/11/04 at pp. 69-73, Robertson Aff., Ex. 9.

69.-71. As acknowledged by the FTC, in November 2001 Stern, not Barrett, forwarded the coral calcium proposal to Trudeau. *See* FTC Statement of Facts, at 69-71. In addition, the proposal made clear that Stern would be responsible for buying all media time and collecting all funds in his merchant account. Moreover, the proposal to Stern did not presume that DMC would answer calls from customers. Rather, the proposal indicated that another incoming call

center, West, might be responsible for performing this function. Stern also was included as a party to the proposed contract. *See* Stern Depo., 1/14/03, at p. 28, Robertson Aff., Ex. 6; Stern Depo., 3/25/02, at pp. 12-13, Robertson Aff., Ex. 7; Stern Depo., 7/15/05 at p. 40, FTC Summary Judgment Exhibit 15; Barrett Depo., 3/25/02, at p. 31, Robertson Aff., Ex. 6.

72.-80. Although Barrett paid a \$25,000 appearance fee to Trudeau to film an infomercial with Robert Barefoot, \$20,000 of which was actually forwarded by Allen Stern, he had no other role whatsoever in its production, editing or final content. *See* Answer and Affirmative Defenses and Counterclaim of Kevin Trudeau, Shop America (USA) LLC and Shop America Marketing Group, LLC, dated January 3, 2003 at page 6 Answer No. 15, Robertson Aff., Ex. 5. Specifically, upon completing the taping of the show at Trudeau's studio in Burbank, California, Trudeau told Barrett that he would have the show edited and reviewed by his professional "FTC" staff and attorneys, and then provide a final "master" tape to Barrett that could be aired immediately. *See* Barefoot Depo., 9/11/04, at pp. 69-73, Robertson Aff., Ex. 9; Barrett Depo., 12/22/03, at pp. 45-46, 49, 59-60, FTC Summary Judgment Exhibit 6. Stern, who also had more experience in the industry than Barrett, informed Barrett as well that he would have the show reviewed by his attorneys before it was aired. *See* Stern Depo., 7/15/05, at pp. 73-80 and Attachment 7, FTC Summary Judgment Exhibit 15. Stern never indicated that the show's content was problematic or lacked substantiation. In addition, the content of the show mirrored the information in Barefoot's books, which was supported by citations to scientific studies and literature. *See* copies of "*The Calcium Factor*" and "*Death By Diet*", Robertson Aff., Exs. 10 and 11; Dr. Voight's *Book on Coral Calcium*, Robertson Aff., Ex. 12; Barefoot Depo., 9/11/04 at pp. 69-73, Robertson Aff., Ex. 9.

81. Although the content of the coral calcium infomercial speaks for itself, the FTC has taken passages of the advertising out of context. The statements in the infomercial are clearly Barefoot's opinions about the benefits of coral calcium, which are well-documented in his books and in the public domain to be substantial. *See* Barefoot Depo., 9/11/04, at pp. 15, 17, 22-23, Robertson Aff., Ex. 9. Moreover, the coral calcium infomercial did not display any product nor did it actively solicit any particular coral calcium product. The infomercial simply depicted Mr. Trudeau interviewing Mr. Barefoot on the benefits of coral calcium. There is no mention of a specific brand of coral calcium. In the infomercial Mr. Barefoot's books are mentioned and shown and Mr. Trudeau directs the viewer to a 1-800 number for "more information." The infomercial makes no reference to any specific product as such, nor does Bob Barefoot endorse any particular product or name. Bob Barefoot simply extols the virtues of coral calcium as a mineral supplement. *See* Barrett Depo., 12/22/03, (Attachment No. 3 Transcript of the Coral Calcium Infomercial at 4, 13, 17; Attachment No 4 Affidavit of Donald Barrett, dated December 8, 2002 at ¶ 11), FTC Summary Judgment Exhibit 6; Barrett Aff., 2/10/06.

82. All information concerning the performance of the coral calcium show was possessed by Stern and communicated to Barrett by Stern. *See* Stern Depo., 1/14/03, pp. 10-11, 27, Robertson Aff., Ex. 9. Thus, while Stern communicated to Barrett that the show was performing well in certain markets, Barrett had no ability to confirm or deny that information, nor did Barrett have any ability to quantify the financial performance of the show. *See* Barrett Depo., 12/22/03, at pp. 86-87, FTC Summary Judgment Exhibit 6; Barrett Depo., 7/21/05 at pp. 28, 34, FTC Summary Judgment Exhibit 7; Barrett Aff., 2/10/06.

83. Neither Barrett nor DMC distributed any free standing inserts for newspapers or magazines. All such advertising was distributed solely by Stern and all proceeds of any such

advertising was collected by Stern. In fact, Steven Ritchey King Media and Triad's Vice President of Operations testified that it was King Media and Triad who created the brand awareness for Coral Calcium Daily. *See* Ritchey Depo., 7/14/05, at p. 141, FTC Summary Judgment Exhibit 16. Stern also told Barrett that he had provided all advertising materials to his staff and attorneys for review. *See* Barrett Depo., 12/22/03 (Attachment No. 7), FTC Summary Judgment Exhibit 6. Moreover, as the FTC concedes, the FTC cannot state with any certainty when, where or for how long the free standing inserts were distributed or published by Stern, except to state that they were disseminated "briefly." *See* FTC Statement of Facts, at 83. In fact it is clear that Susan Graham of Triad created the inserts. *See* Barrett Aff., 2/10/06, Exhibit 1; Stern Depo., 7/15/05 at p. 67, FTC Summary Judgment Exhibit 15. Finally, the content of these inserts was entirely derivative of information contained in Robert Barefoot's books and publications, which Barefoot repeatedly stated and confirmed were supported by a wealth of competent and reliable scientific evidence. *See* Barefoot Depo., 9/11/04, at pp. 15, 17, 22-23, Robertson Aff., Ex. 9; copies of "*The Calcium Factor*" and "*Death By Diet*", Robertson Aff., Exs. 10 and 11. In addition, Stern and Triad, not DMC, filed a trademark application for the name "Coral Calcium Daily." *See* Stern Depo., 7/15/05 at p. 113, FTC Summary Judgment Exhibit 15.

84.-86. DMC acted solely as a "call center" for the coral calcium infomercial, answering telephones and forwarding customer orders to Stern and his companies for processing and fulfillment. These services were performed for a commission. Stern and his companies, however, handled all aspects of the infomercial other than receiving calls, including review of all advertising, media purchasing, selecting the forum and time for advertising, purchasing products from manufacturers, packaging and labeling the products, processing customer orders and

receiving customer funds, and shipping the product. Neither Barrett nor DMC had any control over these functions. In addition, Stern had no written requirement to use Barrett or DMC for inbound calls, and often used other call centers for these services. *See* Barrett Depo., 12/22/03, (Attachment No. 5 at ¶¶ 15-17), FTC Summary Judgment Exhibit 6, at 20-35, 52; Barrett Aff., 6/4/04, Docket No. 9, at ¶¶ 5, 7; Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Barrett Depo., 3/25/02, at pp. 11-14, Robertson Aff., Ex. 6; Stern Depo., 1/14/03, pp. 10-11, Robertson Aff., Ex. 8; Stern Depo., 7/15/05 at p. 28, FTC Summary Judgment Exhibit 15; Ritchey Depo., 2/13/03, Robertson Aff., Ex. 22; Ritchey Depo., 2/13/03, Robertson Aff., Ex. 26.

87. The original scripts, power sheets and other sales literature in connection with the coral calcium infomercial were prepared and provided by Stern, based upon information contained in Barefoot's published and widely disseminated books. *See* Maihos Depo., 4/7/05, at pp. 37-38, FTC Summary Judgment Exhibit 9. Sales representatives were instructed to read Barefoot's book in order to answer questions from customers who had read the book. When certain questions were asked by customers, Barefoot's books and literature were consulted to provide answers according to those resources. *See* Mena Aff., 1/25/06.

88.-93. All information provided to sales personnel was provided to DMC by Barefoot and was often reviewed by Stern. All testimonials were provided by Barefoot and at no time did DMC publish or communicate any testimonial that was not provided by Barefoot and confirmed by Barefoot to be both genuine and received by him in the course of his longstanding campaign to educate the public about the benefits of coral calcium. *See* Barefoot Depo., 9/11/04 at pp. 15, 17, 77, 87, 94, Robertson Aff., Ex. 9. Similarly, any and all statements in any fact sheets about coral calcium provided to the DMC sales staff were provided by Barefoot and mirrored the statements that Barefoot had made in his books or in public discussions. *See* Mena Aff., 1/25/06;

Barrett Aff., 2/10/06. Sales staff were told to state only that “Barefoot states” or Barefoot says in his book,” and not to make any claims themselves that went beyond Barefoot’s opinions. *See* Mena Aff., 1/25/06. At all times, Barefoot claimed he had significant scientific evidence for his published claims, including how coral calcium worked and its absorption rates. *See* Barefoot Depo., 9/11/04 at pp. 17, 77, 87, 94, Robertson Aff., Ex. 9; *see* copy of “*The Calcium Factor*”, at p. 153, Robertson Aff., Ex. 10. The same sales manager relied upon so heavily by the FTC, Erik Limbaugh, also testified multiple times that all information regarding the benefits of coral calcium was provided by Barefoot or discussed by Barefoot in his books. Limbaugh also testified that the information provided to the sales staff was for informational purposes only to respond to specific questions by customers calling in response to Barefoot’s statements in the infomercial. *See* Limbaugh Depo., 5/16/05 at p. 241, FTC Summary Judgment Exhibit 10. Moreover, the FTC’s own citations show that DMC sales staff were explicitly instructed to state that “We do not claim, nor do we guarantee, that the Coral Calcium cures anything.” *See* Maihos Depo., 4/7/05, at pp. 59-60, FTC Summary Judgment Exhibit 9. Similar disclaimers appeared throughout the coral calcium materials provided to the sales staff and sales staff were regularly instructed that they must not make any claims or guarantees that coral calcium would cure any disease. *See* Mena Aff., 1/25/06.

94.-95. DMC sales representatives were explicitly instructed not to make any claims regarding any disease to callers responding to the infomercial and sales representatives were told to tell customers to consult their doctors before taking any dietary supplement. *See* Maihos Depo., 4/7/05, at pp. 59-60, FTC Summary Judgment Exhibit 9; Mena Aff., 1/25/06. Nonetheless, customers often disclosed to the sales representative that they were interested in information about a specific disease. Sales representatives were told repeated that they were to

tell customers that they were not doctors and that they were prohibited from discussing any disease. *Id.* Sales personnel were requested to note the inquiry, however, and fields were added in the DMC database for this purpose. *Id.* The FTC's contention that these fields in the database somehow prompted sales personnel to request disease information is incorrect and is disputed by DMC and Barrett. *See* Barrett Aff., 2/10/06.

96.-97. As testified to in a previous affidavit submitted to the Court, Barrett's father did have cancer and did begin taking coral calcium in connection with that disease. He is still alive today and credits coral calcium with saving his life. *See* Affidavit of Donald Barrett Sr. ("Barrett Sr. Aff."), Docket No. 18. The FTC has not provided any evidence that the statements in the document are not true, or that the statements made by Barrett do not reflect his genuine beliefs at the time. Barrett personally believes passionately in the curative benefits of coral calcium. *See* Barrett Aff., 2/10/06. The FTC's alleged "evidence" to the contrary, consisting of highly questionable and biased "experts" has not changed his beliefs one bit that coral calcium has tremendous health benefits. *Id.*

98. The price of coral calcium varied greatly among different purchase programs and depending on the time period. All of the manufacturing of the product was handled by third parties with significant experience in the dietary supplement field, with certified quality control. At no time has there been any assertion or allegation that the coral calcium purchased by Stern was not of the highest quality and manufactured from marine grade coral. *See* Barrett Aff., 2/10/06. While the FTC has alleged that certain claims made about coral calcium by Barefoot cannot be supported, which DMC disputes, there has never been any allegation that the product sold to customers by Stern was not the product advertised, marine grade coral calcium. Coral calcium is still widely sold in health and convenience stores worldwide by dozens of

manufacturers and distributors. *Id.* Neither the FTC nor the FDA has ever claimed that marine grade coral calcium is not a beneficial health supplement, nor have they alleged that it is harmful in any way. *Id.*

99.-103. Stern, Triad and King Media handled all aspects of the coral calcium advertising and sales, except for answering the telephones when customers called the DMC call center. Stern, Triad and King media purchased all media for the show, purchased all product from manufacturers, received all customer funds and shipped product from its facilities. *See* Barrett Depo., 12/22/03, at pp. 20-35, 52, FTC Summary Judgment Exhibit 6; Barrett Aff., 6/4/04, Docket No. 9, at ¶ 7; Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Barrett Depo., 3/25/02, at pp. 11-14, Robertson Aff., Ex. 6; Stern Depo., 1/14/03, pp. 10-11, 27, Robertson Aff., Ex. 8; Stern Depo., 7/15/05 at pp. 28, 30, 40, FTC Summary Judgment Exhibit 15; Ritchey Depo., 2/13/03, Robertson Aff., Ex. 26. While DMC and Barrett discussed sharing profits with Stern and his companies, Stern never provided any accounting of profits from the show to Barrett or DMC, and Barrett has no basis to know whether any of the funds forwarded by Stern represented profits from the show. To the contrary, Barrett believes that all funds forwarded by Stern were attributable to the call center commissions, and not profits. *See* Barrett Depo., 12/22/03, at pp. 86-87, FTC Summary Judgment Exhibit 6; Barrett Depo., 7/21/05 at pp. 28, 34, FTC Summary Judgment Exhibit 7.

104. All distributors that purchased coral calcium product or media time to run the coral calcium show did so through Stern, Triad and King Media. *See* Stern Depo., 7/15/05 at p. 158, FTC Summary Judgment Exhibit 15. All distributors were unrelated third party businesses that independently purchased Media through Stern and King Media, purchased product through third party manufacturers and sold directly to customers. *Id.*; Sciucco Aff., 9/28/05, ¶ 33, Docket No.

120. The FTC fails to identify any “relationship” between DMC and any third party distributor, such as any contract, ownership or agreement. *Id*

105-107. Until March 2003, just two months before the coral calcium infomercial was pulled from the air, King Media purchased all media time in connection with the show, and neither DMC nor Barrett had any influence on the purchase of that media time, where the show would air, or when. *See* Barrett Depo., 12/22/03, at pp. 39-40, FTC Summary Judgment Exhibit 6. During this period, Stern informed Barrett that he was paying King Media for the media time, and also paying King Media a “commission” for its services. *See* Stern Depo., 1/14/03, pp. 10-20, Robertson Aff., Ex. 8. Stern never provided any accounting of any kind to Barrett regarding these commissions or fees, despite numerous requests. Barrett believes that the vast majority of customer funds were kept by Stern, and, among other reasons, Stern defended his retention of the majority of the funds as commissions for the purchase of media time by King Media. *See* Barrett Depo., 12/22/03, at pp. 86-87, FTC Summary Judgment Exhibit 6; Barrett Depo., 7/21/05 at pp. 28, 34, FTC Summary Judgment Exhibit 7.

108.-109. On several occasions, Stern told Barrett that he had provided a copy of the coral calcium show to his attorney for review and that his attorney had approved the show for airing. *See* Stern Depo., 7/15/05 (Attachment 7), FTC Summary Judgment Exhibit 15. Stern also told Barrett that each of the networks airing the show would review the show for content before they would air the show. *Id*. In addition, Barrett had been told by Kevin Trudeau that he had given the show to his “FTC” legal experts and they had approved the show, and that the show was “perfect”. *See* Barefoot Depo., 9/11/04 at pp. 69-73, Robertson Aff., Ex. 9; Barrett Depo., 12/22/03, at p. 37, FTC Summary Judgment Exhibit 6. Barrett thus believed that the show had been reviewed by at least two experts, who had approved the content and format for

the show. Barrett also believed that the show would be subject to continuous review by each of the stations airing the show. *See Stern Depo.*, 7/15/05, at pp. 65-66, FTC Summary Judgment Exhibit 15; Barrett Aff., 2/10/06.

110. Although it appears that Stern was aware of Trudeau's criminal past as early as February 2002, that information was not communicated to Barrett until months later. Barrett also was not aware that Trudeau had previously entered into a consent decree with the FTC until many months after Stern was apparently aware of this information. *See Barrett Depo.*, 7/21/05 at pp. 28, 34, FTC Summary Judgment Exhibit 7; Barrett Aff., 2/10/06. Notwithstanding Trudeau's criminal past and prior consent decree with the FTC, which the FTC claims he violated in connection with the coral calcium show, as well as the fact that he personally generated revenues of over \$121 million in connection with a later similar coral calcium show featuring Robert Barefoot, called the "Debbie and Kevin Show," the FTC settled with Trudeau for \$2 million. *See Stipulation of Dismissal and Interrogatory Answers, Robertson Aff.*, Exs. 4 and 19; Trudeau Depo., 2/6/03, Robertson Aff., Ex. 24; Transcript of the Debbie and Kevin Show, Robertson Aff., Ex. 23; Malcher Affidavit, 1/13/03, Robertson Aff., Ex. 28. Trudeau is currently one of the top infomercial producers in the United States and continues to air infomercials nationally.

111.-118. In early 2002, Trudeau demanded a larger percentage of the profits from the original coral calcium show and communicated his demand to Barrett and Stern. Stern, who possessed the show and received all the proceeds from the show, communicated to Trudeau that he was not willing to renegotiate the terms of the arrangement. In response, Trudeau had his consultant Richard Zeeb send a letter to Barrett in which he claimed that the current coral calcium show was not compliant in certain respects. Aware that Stern was handling all

communications with Trudeau in connection with the dispute, Barrett forwarded the correspondence to Stern, and asked Stern to have his attorneys review the claims and respond to Trudeau. *See* Barrett Depo., 12/22/03, at pp. 59-61, FTC Summary Judgment Exhibit 6. Stern then communicated to Barrett that he had the show reviewed by his attorneys and Trudeau's assertions were unfounded. Stern also notified Barrett that he would have the show reviewed again and never indicated that the original show was not compliant. *See* Stern Depo., 7/15/05 (Attachment 7), FTC Summary Judgment Exhibit 15. All decisions regarding legal edits to the show and which versions of the show would be aired were made by Stern. To the extent the FTC contends that Barrett decided to run an earlier version of the show after testing a later version, that contention is denied and disputed. *See* Stern Depo., 7/15/05, at pp. 80-83, FTC Summary Judgment Exhibit 15; Barrett Aff., 2/10/06.

119.-120. For a few months in 2003, DMC purchased a small amount of its own media for the coral calcium show and processed customer orders, after a dispute arose between Stern and Barrett over Stern's failure to provide any accounting or other financial information regarding the coral calcium show to Barrett. *See* Barrett Depo., 7/21/05 at pp. 28, 237, FTC Summary Judgment Exhibit 7. The amount of media purchased was limited and the amount of coral calcium sold through the show was a small fraction of the amounts that Barrett believes were collected by Stern and his companies from 2001 through 2003. *See* Barrett Depo., 7/21/05 at pp. 31, 32, FTC Summary Judgment Exhibit 7.

121.-125. Upon being contacted by the FTC in June 2003, DMC immediately pulled the coral calcium infomercial from the air. *See* FTC's Statement of Facts, at ¶ 122. The infomercial has not been run by DMC or any company affiliated with DMC since that time. *Id.* No direct response advertising for coral calcium has been disseminated by DMC since June 2003. *Id.*

Some existing customers, however, continued to purchase coral calcium, a widely available product, after the show no longer ran, as part of their regular renewals of product. Thus, the sales personnel still had available to them some of the information concerning coral calcium derived from Barefoot's books and other published materials. *See* Barrett Aff., 2/10/06.

However, these materials were not used in any fashion in connection with incoming calls from the infomercial, because the infomercial was no longer running. Moreover, these materials continued to emphasize that sales personnel were never to tell a customer that coral calcium would cure any disease, stating "Do not ever tell a customer that any product will cure any disease." *See* Maihos Depo., 4/7/05, at pp. 59-60, FTC Summary Judgment Exhibit 9; Maihos Aff., 6/6/05 (Exhibit 1 page 8), Docket No. 83. In addition, at the time of the first call from the FTC, the DMC Defendants contacted Trudeau and requested that he provide additional substantiation, in addition to the books published by Barefoot. In response, a significant volume of materials were provided. *See* Barrett Aff., 6/4/04, Docket No. 9, and Exhibit C submitted separately to the Court, Docket No. 10 (supporting materials and declaration from Richard Zeeb); Robertson Aff., Ex. 14.

126.-129. The FTC's expert witness submissions in connection with the coral calcium infomercial are disputed by the DMC Defendants. The FTC, not the DMC Defendants, bear the burden of proving that there is no reasonable substantiation for the claims in the coral calcium infomercial. Notwithstanding that the overall information communicated by the infomercial is not false or misleading, the expert reports and testimony submitted by the FTC, which purport to state that there is no scientific evidence for the claims made by Mr. Barefoot concerning coral calcium, are flawed in many respects. There is no requirement that the DMC Defendants submit their own expert testimony concerning the substantiation for coral calcium, only that the DMC

defendants demonstrate that the evidence submitted by the FTC does not meet the FTC's burden of showing that there is no dispute concerning the facts submitted by the FTC's experts, or that the reliance of the DMC Defendants was not reasonable. As demonstrated by the wealth of evidence submitted with this opposition, the FTC has fallen far short of showing that no factual dispute exists. *See Aldrich Aff.*, 2/9/06, and attachments thereto (collecting scientific articles and studies related to coral calcium, calcium and health claims).

130-131. The DMC Defendants dispute the FTC's use of outside "experts" as violative of the First Amendment to the United States Constitution and the Administrative Procedure Act. In essence, the FTC's use of third-party experts to define the required level of substantiation for any particular product is arbitrary and capricious. *See Complaint, Direct Marketing Concepts, Inc. v. FTC*, Case No. 05-11930 GAO (D. Mass.), filed September 23, 2005, attached as Exhibit 1 to Robertson Aff.. Dr. Wood is not an employee of the United States government or the FTC, and his statements are clearly nothing more than his opinions, based upon his review of a select group, but certainly not all, of the published materials on coral calcium publicly available. *See Aldrich Aff.*, 2/9/06 (Exhibit 1). As set forth below, his conclusions are not objective, but are carefully crafted to include only statements helpful to the FTC, while omitting aspects of his research and supporting materials that support the health benefits of coral calcium. Dr. Wood's testimony is not credible, and cannot overcome the FTC's burden to demonstrate that there is no issue of material fact concerning the substantiation for the health benefits of coral calcium. *Id.*

132.-137. The DMC defendants dispute Dr. Wood's conclusions in connection with coral calcium. Contrary to Dr. Wood's conclusions, there is a significant amount of scientific literature and substantiation for the absorption opinions expressed by Barefoot. Dr. Woods himself admits that studies exist that suggest that substantially more absorption occurs with

coral-derived calcium than calcium-carbonate derived calcium. Beyond this study, published studies and literature substantiate the claim that the calcium in coral calcium would be better absorbed than the calcium from a commonly available antacid. For example, the coral calcium discussed by Barefoot contains vitamin D3, which does not exist in a commonly available antacid. It is a known scientific fact that vitamin D3 potentiates the intestinal absorption of calcium. In Dr. Wood's own study, he states that "classic balance studies have to continue for long period, during which the gut gradually adapts to the new calcium intake by changing it's absorptive capacity as a result of alterations in serum 1,25(OH)₂D [Di-Hydroxyvitamin D]." *See* Affidavit of Dr. Richard J. Wood, FTC Summary Judgment Exhibit 24, Attachment 4.

These conclusions are further supported by a randomized double blind clinical trial concluding that calcium is better absorbed from supplemental sources that contain vitamin D3, such as coral calcium (Mortensen 1996). *See* Aldrich Aff., 2/9/06 (Exhibit 1, Binder No. 7, at tab 544).

Finally, if there were any remaining question whether there are issues of fact regarding the scientific studies and literature concerning bioavailability and absorption of coral calcium, Dr. Woods himself concedes that the studies he cites provide "interesting data" for the issues of rate and amount of absorption of coral calcium. *See* Affidavit of Dr. Richard J. Wood ("Wood Aff."), FTC Summary Judgment Exhibit 24.

138. Dr. Wood's conclusions that certain types of studies are "generally accepted" is disputed by the DMC Defendants on several grounds. First, simply because Dr. Wood believes that a certain type of study is more acceptable than another type of study, and may provide, in his subjective view, more reliable information, does not mean that other types of studies or literature cannot provide a reasonable basis for certain opinions about a product. *See* Aldrich Aff., 2/9/06 (Exhibit 1). Dr. Wood's statements regarding "general acceptance" lay bare the fundamental

problems with the FTC's random, arbitrary and capricious approach to reviewing dietary supplement claims. *See* Wood Aff., FTC Summary Judgment Exhibit 24. Dr. Wood is not stating that other means of arriving at data do not exist, only that in his view those means are not as "generally accepted." *Id.* Dr. Wood's subjective testimony cannot remove issues of fact regarding the existing literature and substantiation for claims regarding coral calcium. *See* Aldrich Aff., 2/9/06 (Exhibit 1).

139. For all of the foregoing reasons, as well as the vast amount of literature and studies submitted with this opposition, including Barefoot's books, the DMC Defendants strongly dispute the FTC's contention that Dr. Wood's report demonstrates that there is *no* competent and reliable scientific evidence supporting Barefoot's opinions that the body absorbs coral calcium at a faster rate than commonly available calcium supplements. *See* Aldrich Aff., 2/9/06 (Exhibit 1). To the contrary, many studies, including studies relied upon by Dr. Wood, have concluded that coral calcium absorbs at a significantly faster rate than traditional calcium supplements. *Id.*; Wood Aff., FTC Summary Judgment Exhibit 24.

140.-141. The DMC defendants dispute the contention that Dr. Sowers is an expert on bioavailability of minerals, and dispute her conclusions regarding coral calcium and their relevance to Coral Calcium Daily. Dr. Sowers never discusses the terms "bioavailability" and "mineral" in her report. *See* Declaration of Dr. Mary Fran Sowers, December 6, 2005 ("Sowers Aff."), FTC Summary Judgment Exhibit 25. More importantly, however, Dr. Sowers never states in her report whether or not she has actually seen or read the label for Coral Calcium Daily. *Id.* Dr. Sowers gives no indication in her report if she is aware of the mineral content of Coral Calcium Daily or any other specific coral calcium product. *Id.* The DMC Defendants dispute whether Dr. Sowers is competent to testify about any dietary supplement, including coral

calcium, if she cannot state with certainty that she is aware of all of the ingredients contained in the product. *Id.* Her testimony cannot be used to conclude that there is no issues of fact concerning the health benefits of coral calcium, when her opinions do not appear to be tied to the specific product at issue, and volumes of documentation exist concerning the product. *See* Aldrich Aff., 2/9/06 (Exhibit 1).

142.-147. The DMC Defendants dispute Dr. Sowers opinion that there is no competent and reliable scientific evidence for the opinions expressed about coral calcium. Dr. Sowers' own articles and books make clear that there is evidence that coral calcium may reduce instances of a number of diseases, including cancer. *See* Sowers Aff., 12/6/05, FTC Summary Judgment Exhibit 25. In many of Dr. Sowers' own writings, she evaluated the relationship between nutrition and other environmental factors and the incidence of disease, determining that there is evidence that such a correlation does exist. For example, Dr. Sowers states "that some studies suggest that calcium intake may play a preventative role in the relationship to colorectal cancer." Dr. Sowers also states that some studies have shown that calcium may reduce instances of high blood pressure and heart disease. Dr. Sowers also discusses and cites the Longnecker study, which investigated dietary risk factors for Amyotrophic Lateral Sclerosis (ALS), "an autoimmune disease that affects the brain." This study concluded a "moderately protective associations [against ALS] were suggested for magnesium and lycopene." Magnesium is in coral calcium, but Dr. Sowers would not necessarily have known this because she never read or evaluated the ingredients. Numerous other studies, submitted herewith, have demonstrated a direct beneficial link between coral calcium and a myriad of health problems. These studies and conclusions are conveniently ignored by Dr. Sowers and the FTC, and there is no question there are disputed

issues of fact surrounding her opinions. *See* Aldrich Aff., 2/9/06 (Exhibit 1); Sowers Aff., 12/6/05, Attachments 2 & 11, FTC Summary Judgment Exhibit 25.

148-153. The DMC Defendants dispute Dr. Sowers' statements regarding the Journal of the American Medical Association ("JAMA"). As a preliminary matter, The DMC Defendants dispute the characterization of the claims in the infomercial that Barefoot states that the JAMA article proves that calcium reverses cancer. Rather, Barefoot claims there are published articles discussing some studies connecting calcium and epithelial cancer cells growing back to normal. Submitted in opposition to the FTC's motion are a number of articles and studies from JAMA and other medical journals supporting the health benefits of calcium in connection with incidences of cancer. In addition, the subject JAMA study specifically discusses how "calcium also directly decreases proliferation of colonic and other epithelial cells in vitro and can induce terminal differentiation." Moreover, even the studies and articles that Dr. Sowers cites, including the "Holt Study" published in JAMA and the "Baron Study" in the New England Journal of Medicine, she concedes that these studies demonstrate that "calcium intake may play a preventative role in relationship to colorectal cancer." Similarly, Dr. Sowers concedes that other studies she submitted have demonstrated a link between calcium intake and cancer formation. These concessions alone demonstrates that there are disputed issues of fact regarding the FTC's arguments regarding the health benefits of coral calcium. *See* Aldrich Aff., 2/9/06 (Exhibit 1); Sowers Aff., 12/6/05, Attachments 2-3 FTC Summary Judgment Exhibit 25; Attachment C to Barrett Aff., 6/4/04, Docket No. 10 (declaration of Richard Zeeb and supporting exhibits).

154-156. The DMC Defendants dispute Dr. Sowers' opinions regarding the relationship between calcium intake and blood pressure. As evidenced by the articles and studies submitted with this opposition, there is a wealth of research connecting calcium intake with reduced blood

pressure and a reduced risk of heart disease. These studies are ignored by Dr. Sowers. In addition, Dr. Sowers herself concedes that studies have shown that calcium intake reduces blood pressure. Nonetheless, she tailors her opinion to minimize these studies for the expediency of reaching the result the FTC desires. Without question, Dr. Sowers' own concessions, combined with the numerous issues and studies not addressed by her opinion, result in many disputed issues of fact regarding her conclusions in connection with coral calcium. *See Aldrich Aff.*, 2/9/06 (Exhibit 1); *Sowers Aff.*, 12/6/05, FTC Summary Judgment Exhibit 25.

157. The DMC Defendants dispute Dr. Sowers conclusions regarding the existence of studies discussing coral calcium and other diseases. First, Dr. Sowers concedes that she conducted "several" biologic searches, but there is certainly no statements that her search was comprehensive. Second, her claim that there is "no" scientific research is simply incorrect, as demonstrated by the materials submitted with this opposition. Third, Dr. Sowers never read the ingredients in the actual product she was supposed to be analyzing, undermining her opinions. Finally, Dr. Sowers herself cites the Longnecker study, which investigated dietary risk factors for Amyotrophic Lateral Sclerosis (ALS), "an autoimmune disease that affects the brain." This study concluded a "moderately protective associations [against ALS] were suggested for magnesium and lycopene." Magnesium is in coral calcium, but Dr. Sowers would not necessarily have known this because she never read or evaluated the ingredients. For all of these reasons, there are numerous disputed facts regarding Dr. Sowers' opinions and conclusions. *See Aldrich Aff.*, 2/9/06 (Exhibit 1); *Sowers Aff.*, 12/6/05, Exhibit 11, FTC Summary Judgment Exhibit 25.

158.-161. The DMC Defendants dispute the FTC's evidence regarding recent submissions to the FDA. Contrary to the FTC's argument, the evidence submitted to the FDA does show a direct link between calcium supplements and certain cancers, including colon/rectal

cancer. The FDA itself has concluded that: “Some evidence suggests that calcium supplements may reduce the risk of colon/rectal cancer.” *See* FTC Summary Judgment Exhibit 12, Attachment 7. The materials submitted to the FDA, many of which are being submitted with this opposition, completely undermine the conclusions and opinions of the FTC’s expert witnesses, which state that “no” scientific evidence exists linking coral calcium and the reduction or prevention of certain diseases, including cancer. Clearly, there is a substantial amount of scientific literature discussing the relationship between calcium and the prevention of certain disease, and it is simply not credible to state that no such evidence exists. Although the FDA did not approve all of the claims that were submitted to it for consideration, the evidence submitted to it addressed many, if not all, of the claims challenged by the FTC. At a minimum, this wealth of competing scientific literature makes clear that these issues cannot be decided on a motion for summary judgment. *See* Aldrich Aff., 2/9/06, and attached exhibits.

162.-163. The FTC concedes that it cannot determine with certainty the total amount of sales of coral calcium by Stern. There is therefore a dispute of fact regarding the exact amount of sales of the product. *See* Stern Depo., 7/15/05, at pp. 125-128, FTC Summary Judgment Exhibit 15. Moreover, these sales were all made by Stern and his companies, and all customer funds were collected by Stern. Stern’s accounting has been unable to ascertain any specific amount of sales. *Id.*; *see* Stern Depo., 1/14/03, at p. 47, Robertson Aff., Ex. 8; Barrett Depo., 7/21/05 at pp. 28, 237, FTC Summary Judgment Exhibit 7.

164-165. Supreme Greens with MSM (“Supreme Greens”) is a product developed by Alejandro Guerrero, not by ITV or any company affiliated with ITV. Neither DMC nor ITV themselves manufacture or develop any products. Rather, all products that are advertised by DMC or ITV are existing products. All ingredients in the products and all suggested servings of

the products are dictated by the inventor and/or manufacturer of the product, not DMC or ITV.

See Maihos Aff., 6/4/04, ¶¶ 4-5, Docket No. 11; Bernabei Aff., 1/25/06

166.-168. The DMC Defendants dispute that in connection with the agreeing to produce an advertisement featuring Guerrero that they ever told Gregory Geremesz that they would undertake to substantiate the claims made by Guerrero. To the contrary, in late 2002, Geremesz contacted representatives of ITV Direct and stated that he knew a Dr. Alejandro Guerrero, who had developed a greens product that Mr. Geremesz believed would likely be successful if marketed through an infomercial. ITV Direct reviewed the materials provided by Geremesz and Guerrero, including testimonials by fitness celebrity Tony Robbins, and decided to pursue additional discussions. At all times, Geremesz and Guerrero represented that Guerrero was a doctor and OMD, and operated a clinic in California with regular patients. Geremesz and Guerrero also represented that the greens product developed by Guerrero had been clinically tested on patients in California and had shown tremendous results. *See* Guerrero Depo., 8/16/04 at pp. 151, 153, Robertson Aff., Ex. 17. These representations about Guerrero's background, studies and clinic were not only communicated to the DMC Defendants, but also to his own business partner, Michael Howell. *See* Howell Depo., 8/17/04, at pp. 70-74, Robertson Aff., Ex. 16; Bernabei Aff., 1/25/06 .

169.-170. The DMC Defendants dispute that they handled all aspects of the Supreme Greens program. To the contrary, the Distribution Agreement set forth the respective obligations of the parties, including the formulation, manufacture and delivery of the product, which was the responsibility of Guerrero. Additionally Gregory Germenez testified that he approved artwork for the Supreme Greens Product. *See* Geremesz Depo., 8/18/04 at p. 149, Robertson Aff., Ex. 18. The Distribution Agreement also states that Guerrero will provide complete indemnification

to ITV Direct, its officers, directors, employees and affiliates in the event that any of his claims were later challenged by the FTC or any other federal agency. *See* Barrett Depo., 7/21/05 (Attachment 10), FTC Summary Judgment Exhibit 7. As part of this agreement, and as a condition of agreeing to produce an infomercial featuring Guerrero, Guerrero confirmed that he had competent and reliable scientific evidence and studies for the health benefits of Supreme Greens. *See* Bernabei Aff., 1/25/06. Guerrero further testified that he had in fact treated cancer patients, diabetics, people suffering with chronic fatigue and AIDS with the Supreme Greens product. *See* Guerrero Depo., 8/16/04 at pp. 25-26, Robertson Aff., Ex. 17. In several direct conversations, as well as a presentation to the ITV Direct employees, Guerrero confirmed the results of his patient studies. *Id.*, (Deposition Exhibit 8). ITV and Barrett relied on Guerrero's affirmation of the study and its results. Barrett Supplemental Affidavit, dated February 9, 2006.

171.-179. The DMC Defendants dispute that they did not have anyone review the Supreme Greens infomercial before it aired. On April 11, 2003, Guerrero traveled to ITV Direct's studios in Beverly, Massachusetts to film the infomercial. Prior to filming, Guerrero once again identified himself as a doctor, and stated that he had received his doctorate in Traditional Chinese Medicine in California. As is standard practice, the infomercial filming was unscripted and neither ITV nor Barrett dictated any of the statements by Guerrero, including his statements regarding his credentials, his clinical practice in California or the scientific support for his Supreme Greens with MSM product. All Barrett did in connection with the infomercial was pose questions to Guerrero and elicited his responses. At no time did Barrett ever make any affirmative representation concerning Supreme Greens with MSM or any of the health benefits of the product espoused by Guerrero. *See* Barrett Aff., 2/10/06. In addition, Guerrero's business partner, Michael Howell testified that nothing that was said in the infomercial that was

inconsistent or different with conversations that he had had with Guerrero previously about his background, the product or Guerrero's clinic. *See* Howell Depo., 8/17/04, at pp. 70-74, Robertson Aff., Ex. 16. Nonetheless, after the show was taped and edited, Barrett provided a copy of the final edited show to Guerrero for his review and to once again confirm that he could substantiate the statements in the show. Gregory Geremesz testified that he received a copy of the infomercial and did not have any issues or problems with it. *See* Geremesz Depo., 8/18/04 at pp. 175-176, Robertson Aff., Ex. 18. After reviewing the tape, Guerrero confirmed that he had no changes, believed the show was quite well done, and that he could substantiate every statement he had made in the show. Guerrero also stated that he would provide ITV with this substantiation, but needed to make sure that he was not violating any privacy laws by disclosing clinical and patient information. *See* Bernabei Aff., 1/25/06. Because ITV believed that Guerrero was a doctor with an operating clinic, the contention by the FTC that ITV did not have anyone with a medical or science background review the show before the infomercial went on the air is disputed. *See* Barrett Aff., 2/10/06.

180.-182. The DMC Defendants dispute the FTC's statements regarding Maihos' involvement in the Supreme Greens infomercial. Mr. Maihos had no involvement in the filming or editing of the infomercial, nor did he have any involvement in interacting with Guerrero concerning Guerrero's substantiation of the infomercial. *See* Maihos Depo., 7/20/05 at p. 72, FTC Summary Judgment Exhibit 8. This task was undertaken by others within ITV. Mr. Maihos role in connection with Supreme Greens was limited to back office management, including payroll, finance and shipping. Also, while Mr. Maihos did testify that the documents cited by the FTC would not constitute complete substantiation for the claims made by Guerrero in the infomercial, Mr. Maihos testified that Guerrero repeatedly told Maihos and others that he

had many additional studies and documents substantiating his claims, but that he was not comfortable producing this information until he had reviewed privacy and related concerns. *Id.* at 132, 133; Maihos Aff., 6/4/04 at ¶4, Docket No. 11.

183.-186. The DMC Defendants dispute the FTC's evidence regarding their efforts to obtain substantiation from Guerrero. From September 2003 through 2004, ITV did receive additional materials from Guerrero which appeared to provide some support for the claims he had made in the infomercial, including articles and studies. *See* E. Barrett Maihos Aff., 1/26/06. ITV also requested additional details about Guerrero's study of 200 patients, which had been discussed by Guerrero in conversations with Barrett and other ITV employees, and had been echoed by Tony Robbins in his seminars. *See* Maihos Aff., 6/4/04, (*see* attachment A and attachment B at pp. 40,41), Docket No. 11. Barrett and others were told on several occasions that that the specific patient results and data were confidential. Instead of providing this data, ITV was provided a summary of the study. Given that Guerrero was the speaker in the infomercial making claims, and given the indemnification and other assurances provided by Guerrero in connection with the infomercial, Barrett disputes that he did not have reasonable assurances regarding the basis for Guerrero's statements in the infomercial at the time they were made and during the period the infomercial was aired. The testimony of Erik Limbaugh regarding what he had heard about Guerrero's study, which is clearly hearsay and is not admissible for any purpose, should be stricken and is disputed by the DMC Defendants. At no time prior to April 2004 was Barrett informed that Guerrero's study was not credible, or that Guerrero could not produce the studies that he had discussed previously on numerous occasions. *See* Barrett Aff., 2/10/06.

187. While Barrett was aware during 2003 that the FTC had raised concerns about the coral calcium infomercial, he believed the primary reason the show was being scrutinized was because it featured Kevin Trudeau, who had had problems in the past with the FTC. In addition, in part because of the FTC's concerns over the coral calcium infomercial, Barrett had additional discussions with Guerrero regarding his claims and the substantiation for those claims. It was in these conversations that Guerrero assured Barrett that he possessed substantiation for his opinions in the show, including clinical data and research involving 200 patients. *See Barrett Aff.*, 2/10/06.

188.-194. The DMC Defendants dispute the FTC's recitation of the contents of the Supreme Greens advertising. As the FTC is aware, there were well over 30 different versions of the Supreme Greens show that ran during the relevant period, all of which had different content, disclaimers and other information. *See* ITV Direct's Answer to Interrogatories, No 2, dated January 21, 2005, Robertson Aff., Ex. 14. In addition, certain stations required additional disclaimers and other stations required edits to content. Thus, additional versions may exist at many of the stations that ran the show. Moreover, although the content of the version of the Supreme Greens infomercial submitted by the FTC speaks for itself, the FTC has taken passages of the advertising out of context, and the FTC's recitation of these passages is misleading. The statements challenged in the infomercial are also entirely those of Guerrero, express his opinions, and are disclosed as such. The DMC Defendants dispute that the overall impression left by the show, in its entirety, is misleading or creates a false impression. The show contained express disclaimers noting that it was a paid advertisement, that results may vary, and that the product was not a cure for any disease. *See* Affidavit of Luke Goljan, June 4, 2004 ("Goljan Aff."),

Docket No 13, Attachment A. These disclaimers ran throughout the show, and were also required by the stations that ran the shows. *Id.*

195. The DMC Defendants dispute the FTC's evidence concerning the website www.todayshealth.com/supremegreens. ITV had virtually no web sales for the product, because of a dispute that arose between ITV and Guerrero. Specifically, although Guerrero had agreed to "point" the Supreme Greens website to ITV, he did so only briefly and then regained control over the site. Thus, the vast majority of web sales were made directly by Guerrero and he controlled all of the content of the website, including all claims and disclaimers on the site. The FTC also fails to cite the disclaimers on the Today's Health website, which expressly disclaimed that any of the products on the site could treat, prevent or cure any disease. *See E. Barrett Maihos Aff.*, 1/26/06.

196.-203. The DMC Defendants dispute the FTC's evidence regarding information provided to sales representatives, and the source of that information. As testified to by Erik Limbaugh, all information provided to the sales representatives concerning Supreme Greens was generated and provided by Guerrero, and was derivative of the statements and opinions that Guerrero had expressed in the infomercial. *See Limbaugh Depo.*, 5/16/05 at pp. 8, 241, FTC Summary Judgment Exhibit 10. No information was included in any document provided to the sales representatives that was not derivative of information provided by Guerrero and which he had approved. In addition, on several occasions Guerrero visited the offices of ITV, spoke directly to the sales representatives and answered questions. In these discussions, one of which was recorded, he reaffirmed all of the information in the infomercial, discussed his clinical studies and results at length, and referred to himself as a doctor. *See Maihos Aff.*, 6/4/04, Docket No. 11, Attachment B. In addition, all sheets discussing "Frequently Asked Questions" were

prepared from questions posed by customers. *Id.* The responses to these questions were drafted in conjunction with Guerrero and represent solely the opinions and statements of Guerrero in response to these questions. *See* Limbaugh Depo., 5/16/05 at p. 241, FTC Summary Judgment Exhibit 10; Barrett Depo., 7/21/05, at p. 173 and Attachment No. 3 (Meeting Minutes dated September 9, 2003), FTC Summary Judgment Exhibit 7. Because the content of the scripts was entirely derivative of Guerrero's statements and opinions, the DMC Defendants dispute that Barrett was the primary person responsible for the content of the scripts and similar materials. Erik Limbaugh testified that the scripts changed often and he was not entirely sure whether Mr. Barrett was aware of such changes or who actually changed or created the scripts. *See* Limbaugh Depo., 5/16/05 at pp. 20-21, FTC Summary Judgment Exhibit 10; Barrett Depo., 7/21/05, at pp. 169, 170, FTC Summary Judgment Exhibit 7

204.-205. The DMC Defendants dispute the FTC's evidence regarding undercover calls made to the DMC sales floor. As became apparent during discovery in this case, the FTC made dozens of calls to the DMC sales floor. Some of these calls were recorded and others were apparently not recorded. In other proceedings in this case, it has become clear that the FTC has selected only certain calls to place before the Court, in an effort to argue that these select calls are representative of the overall calls. *See* Docket Nos. 110-111. To the extent that the FTC seeks to establish any pattern or course of conduct from any one selected call, the DMC Defendants dispute that evidence. In addition, all information provided to the sales floor is derivative of statements and opinions expressed by Guerrero, which were reviewed and approved by Guerrero. At all times, Guerrero claimed, and told the sales personnel that he possessed the substantiation for, his opinions. *See* Bernabei Aff., 1/25/06.

206. Prices for Supreme Greens varied by purchase plan and period of time that the product was sold. At all times, the price for Supreme Greens was comparable to other greens products being sold in the marketplace. At various points in time, Supreme Greens was sold at prices below \$32.98.

207. The DMC Defendants dispute that stations refused to run the Supreme Greens infomercial solely because cancer was discussed in the show. Every station reviews the content of infomercials before they will agree to run the show. *See* Stern Depo., 7/15/05, at pp. 65-66, FTC Summary Judgment Exhibit 15. In conducting this review, stations often raise questions and issues regarding the content of the show. Stations also often request that additional disclaimers be added to the show or that edits be made for a variety of reasons. *Id.*; *see* Goljan Affs., Docket Nos. 13, 90. While a number of stations asked questions regarding the use of the term cancer in the show, many of these stations nonetheless allowed the show to air, concluding that the overall impression of the show did not result in any direct claim that Supreme Greens could cure cancer, but rather that a healthy lifestyle including dietary supplements containing the ingredients in Supreme Greens would reduce the risk of a number of diseases, including cancer. *Id.*; Barrett Aff., 2/10/06.

208. The DMC Defendants dispute that the FTC ever stated that they would refuse to continue discussing a resolution of the coral calcium claims unless ITV ceased airing the Supreme Greens infomercial. To the contrary, the FTC stated that ITV needed to obtain substantiation for the claims in the show, or needed to edit the show to meet the level of substantiation that ITV did possess at the time, or to remove any claims that in the FTC's view were overly controversial. Counsel for ITV stated that these concerns would be communicated

to ITV, and that ITV would review the show for content. *See* ITV Direct's Answer to Interrogatories, January 21, 2005, Robertson Aff., Ex. 14; Barrett Aff., 2/10/06.

209-231. The DMC Defendants dispute the entire recitation by the FTC of the chronology of events concerning the creation of edited versions of the Supreme Greens show, the airing of the edited show, the filming of an entirely new show with Guerrero, and the FTC's claim that the DMC Defendants ran the "original" show after the edited show was sent to the FTC in November 2003. The FTC's evidence in connection with these allegations has been directly disputed by Barrett and others, and demonstrates that the FTC has fundamentally misunderstood the documents that they have reviewed and have placed before the Court. As the FTC is well aware, there were over 30 versions identified of the "original" Supreme Greens show but edited for content and length. *See* ITV Direct's Answer to Interrogatories, January 21, 2005, Robertson Aff., Ex. 14. Two other tapings were conducted with Guerrero, one with a daytime backdrop, and another with the same nighttime backdrop. *Id.* Footage from both of these taping was also preserved in archive. After the FTC's concerns with the Supreme Greens show were communicated to the DMC Defendants, edits were made to the original nighttime show. At the same time, ITV filmed another show with Guerrero using the daytime backdrop. Several other versions of each show were also dubbed, using pieces of the old shows and some new footage. The night version was referred to internally at DMC and by Barrett as the "original" version of the infomercial. *Id.* That version was edited at least a dozen times during 2003 and 2004, including edits suggested by the FTC. In 2004, ITV began replacing the "original" night version with the day version. However, when that version was unsuccessful, the company decided to return to the "original" version, i.e. the night version. That version, however, would have included dozens of subsequently edited tapes, including the tapes modified

in light of the FTC's concerns. *Id.* The FTC's citation, therefore, to emails referencing the "original" version of the infomercial as proof that the unedited version was run after the FTC's review is flawed and incorrect. Similarly, the FTC's citation to Barrett's deposition testimony that the "original" version of Supreme Greens infomercial was referred to as SGRN is disputed, because Barrett referred to all of the night versions as the "original" version, which would have included versions edited in connection with the FTC's requests. *See Bernabei Aff.*, 1/25/06. The FTC's evidence is also disputed because by its own admission, dozens of versions of the Supreme Greens show were dubbed and sent to stations. The records relied upon by the FTC to purportedly demonstrate that the "original" unedited show ran do not support the FTC's statement of fact, because a number of versions of each show were placed under the monikers SGRN, SGAA, SGBB, SGCC, SPGN and other codes, and the media and dubbing department has testified that, at that time, the data was not reliable. *See Mena Depo.*, 4/8/05 at pp. 48-49, FTC Summary Judgment Exhibit 21; Barrett Depo., 7/21/05, and exhibits attached thereto, FTC Summary Judgment Exhibit 7. Stations also often failed to replace newly sent edited shows, resulting in the old show being run, despite an express direction to replace the old version. *See Barrett Depo.*, 7/21/05, at p. 118, FTC Summary Judgment Exhibit 7. For all these reasons, while the first version of the Supreme greens show may have run after the FTC raised concerns, the DMC Defendants dispute that they ever intentionally ran the unedited show during this period. *Id.* at 150-152.

232.-233. The DMC Defendants dispute the FTC's recitation of the facts surrounding the FDA's review of DMC's and ITV's facilities in 2004. On February 11, 2004 an investigator from the United States Food and Drug Administration ("FDA") conducted an inspection of ITV's existing inventory of Supreme Greens with MSM. The FDA's inspection continued over

the next several months, and ITV provided the FTC with samples of all its products, access to all of its records and a comprehensive tour of its facilities. There was never any effort to hide anything from the FDA, and the investigator was provided complete answers to all of her questions. After months of investigation, the FDA issued a Warning Letter on April 19, 2004, which identified certain advertising and labeling issues, but did not identify any health problems with the product or any problem with the manufacture or ingredients in the product. FTC Statement of Facts, at 232. The FDA also did not raise any questions about the television advertising for Supreme Greens, but did raise some issues with some of the written materials that had been provided by Guerrero and included with the product packages. *Id.* ITV subsequently addressed all of the FDA's concerns and responded by letter dated May 10, 2004. On May 12, 2004, the FDA responded by stating that ITV's proposed corrective action "appears to be adequate." The FDA has not raised any concerns with ITV's or DMC's business or advertising since that time. *See* Barrett Aff., 6/4/04, and Exhibits attached thereto, Docket No. 80; Letter from FDA, attached as Exhibit 22 to Robertson Aff.

235.-238. The FTC's expert witness submissions in connection with the Supreme Greens infomercial are very much disputed by the DMC Defendants. The FTC, not the DMC Defendants, bear the burden of proving that there is no reasonable substantiation for the opinions expressed by Guerrero in the Supreme Greens infomercial. Notwithstanding that the overall information communicated by the infomercial is not false or misleading, the expert reports and testimony submitted by the FTC, which purport to state that there is no scientific evidence for the health claims made by Guerrero concerning the ingredients in Supreme Greens, are flawed in many respects. There is no requirement that the DMC Defendants submit their own expert testimony concerning the substantiation for Guerrero's opinions, only that the DMC defendants

demonstrate that the evidence submitted by the FTC does not meet the FTC's burden of showing that there is no dispute concerning the facts submitted by the FTC's experts. As demonstrated by the wealth of evidence submitted with this opposition, the FTC has fallen far short of showing that no factual dispute exists. *See Aldrich Aff.*, 2/9/06 (Exhibit 1).

239.-242. The DMC Defendants dispute the FTC's use of outside "experts" as violative of the First Amendment to the United States Constitution and the Administrative Procedure Act. The FTC's use of third-party experts to define the required level of substantiation for any particular product, or the ingredients in such products, is arbitrary and capricious. Dr. King is not an employee of the United States government or the FTC, and his statements are clearly nothing more than his opinions, based upon his review of a select group, but certainly not all, of the published materials on the ingredients in Supreme Greens. Dr. King's training is also limited and does not qualify him to speak on many of the issues for which he is proposed by the FTC as an expert. For example, Dr. King is not however an expert on gastroenterology and could not be expected to be current with the standard of research on intra-luminal conditions and how they may be associated with some diseases arising from the gut (such as colorectal cancer). As the research and studies submitted by the DMC Defendants demonstrate, Dr. King's conclusions are not objective, but are carefully crafted to include only statements helpful to the FTC, while omitting aspects of his own research and supporting materials that support the opinions expressed in the Supreme Greens infomercial. In his efforts to assist the FTC in "winning at all costs," Dr. King's testimony is not credible, and cannot overcome the FTC's burden to demonstrate that there is no issue of material fact concerning the substantiation for the health benefits of the ingredients in Supreme Greens. *See Aldrich Aff.*, 2/9/06 (Exhibit 1).

243.-246. The DMC Defendants dispute each and every one of Dr. King's conclusions regarding the body's alkalinity and its relationship to any number of diseases. Dr. King cites to no scientific literature, instead basing all of his conclusions upon his education, "experience," and "knowledge" alone. Reading Dr. King's report, it is also clear that it is very carefully drafted to avoid certain issues, because of the significant scientific support and substantiation for those issues. The vast amount of information and studies that he has not cited in his report provide support for, rather than undermine, the conclusions he advances. For example, one report from the Journal of Nutrition and Cancer stated in 1990 that, "a high fat diet has been recognized for some time as a major risk factor for colon cancer. It is thought that the fat promotes this disease *by increasing the levels of fatty and bile acids* within the colon. These acids irritate and damage the epithelial cells of the colon." See Aldrich Aff., 2/9/06 (Exhibit 1, Binder 3, Study 198). The same paper also recognized that certain supplements have been proposed as a dietary intervention for individuals at high risk of colorectal cancer "because of its ability to reduce rectal epithelial cell proliferation through the binding of fatty and bile acids." *Id.* In another example a recent study stated that "Recent studies have shown that the gastroesophageal junction (GEJ) is regularly exposed to concentrated gastric acid and to a variety of nitrosating species, noxious agents that may contribute to carcinogenesis in this region." *Id.* at Exhibit 1 (Binder No. 7, Study 543). Other studies that support these conclusions, and undermine Dr. King's claims that "no" such literature exists, are being submitted with this opposition. The DMC Defendants also note that Dr. King's conclusions are based on his subjective view of what other physicians believe is "typical." This testimony alone demonstrates an issue of fact as to whether Dr. King's conclusions are based upon the proper standard. For example, the pH within the lumen of the alimentary canal is often very different

from that of the blood, and the systems cited by Dr. King do not control the pH of the lumen of the alimentary canal. *See* Aldrich Aff., 2/9/06, (Exhibit 1); Declaration of Dr. Landon S. King, December 7, 2005 (“King Aff.”), FTC Summary Judgment Exhibit 26.

247.-248. The DMC Defendants dispute Dr. King’s opinion of the type of study that would be conducted by “reasonable” scientists. Although Dr. King’s proposed method would be one reasonable approach, support for an alkalizing effect of the ingredients in Supreme Greens could come from other sources, such as animal and in-vitro studies. These other methods have been accepted by the FDA. These other studies have show a direct link between the ingredients in Supreme Greens and reduced alkalinity. For example, Dr. Michael Murray ND states that “spinach [in Supreme Greens] is also one of the most alkaline producing foods, making it useful to regulate body pH”. *See* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 35, Chapter Spinaciaoleracea Study No. 3.) This is just one example of the available support for the alkalizing effect of Supreme Greens. *See* King Aff., FTC Summary Judgment Exhibit 26.

249.-252. The DMC Defendants dispute the FTC’s statements regarding the conclusions reached by Dr. King. The FTC contends that Dr. King affirms that there is “no scientific evidence,” connecting acidity to a higher risk of cancer and other diseases, and “no circumstances” where medical professionals prescribe reducing acidity to prevent the occurrence of various medical conditions. As demonstrated by the materials submitted by the DMC Defendants, Dr. King’s statements are simply untrue, and there is evidence, even in the materials he cites, connecting reduced acidity with lower incidence of certain diseases, including cancer. Furthermore, additional studies establish that the ingredients of Supreme Greens may be beneficial toward cancer heart disease and diabetes. *See* Aldrich Aff., 2/9/06 (Exhibit 1); King Aff., FTC Summary Judgment Exhibit 26.

253.-264. The DMC Defendants dispute the opinions and conclusions expressed by Dr. Cassileth concerning the ingredients contained in Supreme Greens. Contrary to the opinions expressed by Dr. Cassileth, numerous studies support the health properties of these ingredients and Dr. Cassileth's statements that "no" such studies or literature exists is easily disputed. Moreover, Dr. Cassileth's own citations often contradict the opinions expressed. The evidence demonstrates that there is support for an association of these ingredients with reduced effects of heart disease, cancer, diabetes and arthritis. Examples of specific examples of disputes concerning Dr. Cassileth's opinions about the ingredients in Supreme Greens are as follows:

Alfalfa: Dr. Cassileth states that no studies advocate any sort of medical value for alfalfa in connection with the subject diseases. *See* Declaration of Dr. Barrie Cassileth, December 6, 2005 ("Cassileth Aff."), FTC Summary Judgment Exhibit 27, attachment 3, page 1. In the Rosenthal paper, however, it is stated that L-canavanine (contained in medicago sativa, alfalfa) "has demonstrative antineoplastic activity against a number of animal bearing carcinomas and cancer cell lines." *See* Aldrich Aff., Exhibit 1 (Binder 29, ch. Medicago Sativa II, Tab 5 (Rosenthal 2000)). Another study on alfalfa saponins speaks to a benefit toward high cholesterol and related heart disease. The paper concluded "The data suggest that alfalfa top saponins may be of use in the treatment of patients with hypercholesterolemia." *See* Aldrich Aff., Exhibit 1 (Binder 29, ch. Medicago Sativa II, Tab 4 (Mallinow 1981)).

Aloe: Dr. Cassileth states that no studies advocate any sort of medical value for diabetes; Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1. However, a recent study showed that an extract of Aloe lowered blood sugar in an animal model of diabetes. *See* Aldrich Aff., Exhibit 1 (Binder 26, ch. Aloe Barbdensis, Tab 11 (Rajaseekaran 2005)).

Barley: Dr. Cassileth concedes that dietary barley has been shown to lower blood glucose levels. Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1. However, he also states there is no evidence of any benefit toward heart disease or weight loss potential with barley, which is untrue. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27. A 2003 human trial established that dietary barley “significantly lowered plasma total and low density lipoprotein cholesterol and reduced plasma triacylglycerol concentration.” *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. Hordeum Vulgare II, DBCT (Li 2003)). Likewise, in a recent randomized double blind human trial it was established that an herbal extract containing barley as its primary ingredient “resulted in a significant decrease in parameters such as body weight, waist and hip circumference, and body mass index.” *See* Aldrich Aff., Exhibit 1 (Binder 28, c. Hordeum Vulgare, DBCT (Ignatovich 2000)). The study concluded that “the experimental results indicate a great potential for the use of this herbal preparation in the treatment of human obesity” (*Id.*). This study is particularly poignant in regards to these matters as it is precisely the type of study Dr. Cassileth describes as necessary to support a claimed effects of a dietary product, namely “a double blind, placebo controlled study.” *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, page 9. It is also precisely the type of study that Dr. Cassileth states he was unable to find in connection with Supreme Greens “or any substantially related product.” (*Id.*)

Beet: Dr. Cassileth states that no studies advocate any sort of medical value of the categories at issue here in connection with beets. Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1. Like many other ingredients in Supreme Greens, however, beets have been shown to lower cholesterol. A 1994 study confirmed the “hypocholesterolemic effect of dietary beet fiber.” *See* Aldrich Aff., Exhibit 1 (Binder 26, ch. Beta Vulgaris, Tab 2

(Sonoyama 1994)). Similarly, in *The Encyclopedia of Healing Foods*, Dr. Michael Murray said the following of beets “The pigment that gives beets their rich purple crimson color, betacyanin, is a powerful cancer fighting agent”. See Aldrich Aff., Exhibit 1 (Binder 26, ch. Beta Vulgaris, Tab 3 (Murray 2005)).

Billberry: Dr. Cassileth concedes that dietary bilberry has been shown to prevent diabetic retinopathy. Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1.

There is also evidence bilberry extract lowers blood sugar even when given concurrently with injections of glucose. See Aldrich Aff., Exhibit 1 (Binder 30, ch. Vaccinium Myrtillus II, Tab 2 (Murray 2005)).

Broccoli: A considerable amount of evidence confirms that dietary broccoli has anti-cancer value. Dr. Cassileth concedes that epidemiological studies have confirmed this. Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1. This result is confirmed in a number of other studies submitted in connection with the DMC Defendants’ opposition. See Exhibits attached to Aldrich Aff.

Carrot: Dr. Cassileth claims that no studies demonstrate any benefit from carrots in connection with the categories at issue. See Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1. Epidemiological studies, however, have observed a strong connection between “beta-carotene intake and reductions in the incidence of lung cancer. Carotenoid intake has been associated with a reduced lung cancer risk in 8 of 8 prospective studies and in 18 of 20 retrospective studies”. See Aldrich Aff., Exhibit 1 (Binder 28, c. Daucus Carota II, Tab 3 (Hughes 2004)). A 1995 study of 1300 elderly people established that people consuming one serving a day of carrots had a 60% reduction of the risk of a heart

attack versus people who had less than one serving of carrots a day. *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. *Daucus Carota*, Tab 2 (Gaziano 1995)).

Celery: Dr. Cassileth claims that no studies demonstrate any benefit from celery in connection with the categories at issue. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1. A recent study with a celery seed extract “gives ample evidence of efficacy of methanolic extract of celery seeds as potential anticarcinogenic and antiproliferative agents.” *See* Aldrich Aff., Exhibit 1 (Binder 26, ch. *Apium Claveolens*, Tab 1 (Sultana 2005)).

Cornsilk: Dr. Cassileth claims that no studies demonstrate any benefit from cornsilk in connection with the categories at issue. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 1. Work carried out by Dr. Ryuichirio Suzuki and colleagues, however, “indicated that the water extract of the title material [*Zea Mays* or Cornsilk] suppressed the progression of diabetic glomerular sclerosis”. *See* Aldrich Aff., Exhibit 1 (Binder 30, c. *Zen Mays*, Tab 2 (Suzuki 2005)).

Dandelion Dr. Cassileth claims that there are no studies that support the use of dandelion for any of the aforementioned disease. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 2. He further states there is no evidence of any weight loss potential with this or any other ingredient of Supreme Greens. A study by Dr. Kensuke Baba, however, noted “[a] non-dialysable hot water extract with anti-tumor properties was isolated from dandelions”. *See* Aldrich Aff., Exhibit 1 (Binder 20, ch. *Taraxacum Officinale II*, Tab 1 (Baba 1980)). Another study demonstrated the ability of the plant to lower blood sugar in healthy mammals (monograph paper on dandelions, attached to Aldrich Aff.). Finally it was discovered over 30 years ago that the diuretic components of dandelion can lead to decrease

in weight by up to 30% in animals. *See* Aldrich Aff., Exhibit 1 (Binder 30, ch. Taraxacum Officinale II, Tab 3 (Racz-Kotilla 1974)).

Echinacea Dr. Cassileth alleged that no studies support its use for any of the aforementioned diseases. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 2. A 1992 human study of echinacea and two other immune stimulants in patients with advanced colorectal cancer noted that: “The increase of CD3+ cells and the CD4+ subset after low dose cyclophosphamide which has not been described so far could be attributed in part to echinacin (sic).” *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. Echinacea Purpurea II, Tab 9 (Lersch 1992)). A more recent paper that reviewed the evidence for an anti-cancer benefit for Echinacea stated the following: “Our work over the past 5 years has led to conclusive answers to some of these questions, at least in mice. Our results have shown that daily consumption of Echinacea is indeed prophylactic, extends the lifespan of aging mice, significantly abates leukemia and extends the life span of leukemic mice. Given that human are 97% genetically common with mice and that virtually all our basic physiology is identical, it is neither unjustified to extrapolate these observations to humans...”. *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. Echinacea Purpurea, Tab 4 (Miller 2005)).

Garlic: Dr. Cassileth contradicts her denials that any ingredient in Supreme Greens is helpful in connection with any of the aforementioned diseases when he concedes that garlic intake is associated with a reduced risk of several types of cancer and is helpful against a number of cardiovascular and related conditions. Cassileth states: “Garlic may help preserve the elasticity of the aorta, and it can reduce plasma lipid levels, moderately lower hypertension.” *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 2. Beyond the evidence cited by Dr. Cassileth, a randomized trial confirmed Garlic’s ability

to lower cholesterol in normal patients and patients with heart disease. In that study Dr. Arun Borida concluded “garlic has shown a distinct hypolipidemic action in both healthy individuals and patients of coronary heart disease.” *See* Aldrich Aff., Exhibit 1 (Binder 26, ch. Allium Sativum, Tab 10 (Borida 1981)).

Ginger: While Dr. Cassileth asserts that the one study he cites did not establish ginger as an effective treatment for arthritis, a statistically significant effect of ginger extract could be demonstrated from this data. *See* Aldrich Aff., Exhibit 1 (Binder 30, ch. Zingiber Officinale II, Tab 3 (Bliddal 2000)). This association is also supported by results from another randomized double blind trial with Atrisin, a herbal extract containing ginger and two other ingredients, that showed significant improvements on spontaneous pain in patients with Osteoarthritis and Rheumatoid Arthritis. *See* Aldrich Aff., Exhibit 1 (Binder 30, ch. Zingiber Officinale II, Tab 13 (Sohail 2005)). This last study is particularly poignant in regards to these matters as it is precisely the type of study Dr. Cassileth describes as necessary to support a claimed result of a dietary product, “a double blind , placebo controlled study.” *See* Cassileth Aff., at page 9, FTC Summary Judgment Exhibit 27. It is also precisely the type of study that Dr. Cassileth alleges he was unable to locate. *Id.* Finally, published case reports attest to efficacy of ginger at relieving pain associated with various types of arthritis. *See* Aldrich Aff., Exhibit 1 (Binder 30, ch. Zingiber Officinale II, Tab 14 (Srivastava 1989)). Beyond arthritis, a number of studies not identified by Dr. Cassileth and included with the DMC Defendants opposition support its usefulness against cancer and heart disease. A 1999 study in the British Journal of Cancer concluded that several ginger species “could contribute in the development of cancer prevention methods at the tumor promoting stage.” *See* Aldrich Aff., Exhibit 1 (Binder 30, ch. Zingiber Officinale II, Tab 15 (Vimala 1999)). Results from

animal studies have shown ginger reduces atherosclerosis (a heart disease) and may lower serum cholesterol. *See* Aldrich Aff., Exhibit 1 (Binder 30, ch. Zingiber Officinale II, Tab 7 (Fuhrman 2000) and Tab 2 (Bhandari 1998)).

Goldenseal Dr. Cassileth states that there is no evidence that goldenseal is helpful against major diseases as claimed by Supreme Greens promoters. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 2. This is not true, as Berberine, a chemical found in goldenseal, has demonstrated cardiovascular effects which “suggest its possible clinical usefulness in the treatment of arrhythmias and or heart failure.” *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. Hydrastis Canadensis, Tab 2 (Lau 2001)). A monograph on goldenseal also stated: “Concerning the herb’s anticancer activity, its alkaloids are thought to activate macrophages, thus inducing cytostatic activity against tumor cells.” *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. Hydrastis Canadensis II, Tab 6 (Snow 1998)).

Grapefruit: Dr. Cassileth states that no studies support grapefruit for any of the aforementioned diseases. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 2. A human study conducted by Dr. James J Cerda on grapefruit pectin, however, concluded “that grapefruit pectin and other food sources rich in pectin are useful adjuvants to a fat restricted diet in hypercholesterolemic patients.” *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. Citrus Paradisi, DBCT (Cerda 1998)). An earlier randomized double blind trial conducted by the same group concluded that “a grapefruit pectin-supplemented diet, without change in lifestyle, can significantly reduce plasma cholesterol.” *See* Aldrich Aff., Exhibit 1 (Binder 28, ch. Citrus Paradisi II, Tab 2 (Cerda 1988)). This last study is particularly poignant in regards to these matters as it is precisely the type of study Dr. Cassileth describes as necessary to support a claimed result of a dietary product, “a double

blind , placebo controlled study.” *See* Cassileth Aff., at page 9, FTC Summary Judgment Exhibit 27. It is also precisely the type of study that Dr. Cassileth alleges he was unable to locate. *Id*

MSM: Dr. Cassileth states that “There are no studies that support the use of MSM for any of the aforementioned disease.” *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 2. This is not true. MSM has been shown to help with arthritis in a recent double blind trial. The researchers concluded MSM “improved symptoms of pain and physical function during the short intervention without major adverse affects.” *See* Aldrich Aff., Exhibit 1 (Binder 29, ch. MSM, Tab 5 (Kim 2005)). This study is also a double blind , placebo controlled study which Dr. Cassileth alleges he was unable to locate. Even more remarkable is the fact that the study is the first paper listed in a pubmed search for the words “MSM” and “arthritis.” *See* Aldrich Aff., 2/9/06 (Exhibit 1).

Parsely: Dr. Cassileth stated that There are no studies that support the use of parsley for any of the aforementioned diseases. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 2. This is not true. A 2005 study stated that “It was concluded that probably due to its antioxidant property, parsley extract has a protective effect comparable to glibornuride against hepatotoxicity caused by diabetes.” *See* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 29, ch. Petroselinum Crispum, Tab 3 (Ozsoy-Sacan 2005)).

Pau d’ Arco: Dr. Cassileth cites a 30 year old study that found no benefit with this ingredient. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27. Dr. Cassileth ignores papers subsequently published that are included here that do speak to a benefit. Studies with lapachol and beta-lapachone (chemical constituents of tabebuia species, Pau d’ Arco (*see* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 30, ch. Tabevia Heptaphylla Avelianedae, Tab 2

(Oswald 93/94)), have demonstrated that “Beta-Lapachone selectively induces apoptosis [cell death] in cancer cells without causing the death of non transformed cells in culture” (*see* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 30, ch. Tabevia Heptaphylla Avelianedae, Tab 5 (Li 2003)) and that “we can conclude that lapachol has a great potential of application in fighting metastasis” (*see* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 30, ch. Tabevia Heptaphylla Avelianedae, Tab 6 (Balassiano 2005))).

Peppermint: Dr. Cassileth states that there are no studies that support the use of peppermint for any of the aforementioned diseases. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 3. Since Dr. Cassileth submitted his affidavit, a recent study on peppermint concluded: “The Chemopreventative action and antimutagenic effects observed in the present study is attributed to the antioxidative and radical scavenging property of Mentha extract.” *See* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 29, ch. Mentha Piperita, Tab 5 (Samarth 2005)).

Rosemary: Dr. Cassileth stated that “No studies support the use of rosemary for any of the aforementioned diseases.” *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 3. This statement is not true. A 1997 paper states that: “Natural polyphenols found in rosemary have not only potent antioxidant activities but also anticarcinogenic properties”. *See* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 29, ch. Rosmarinus Officinalis, Tab 5 (Offord 1997)). A 1994 paper also discusses the “hyperglycemic and insulin release inhibitory effects of Rosmarinus officinalis.” *See* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 29, ch. Rosmarinus Officinalis, DBCT (al-Hader 1994)).

Sage: Dr. Cassileth concedes that sage may have hypoglycemic effects. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 3. Beyond the in vitro study he

cites, subsequent data from animal studies confirm this finding. For example, a 2005 paper concluded “The present data indicate that sage extract has hypoglycaemic effects on diabetic animals and the plant should be considered in future therapeutic research.” *See Aldrich Aff.*, 2/9/06, Exhibit 1 (Binder 29, ch. *Salvia Officinalis*, Tab 2 (Eidi 2005)).

Shavegrass: Dr. Cassileth states that “No studies support the use of shavegrass for any of the aforementioned diseases.” *See Cassileth Aff.*, FTC Summary Judgment Exhibit 27, attachment 3, page 3. However a Chinese paper submitted with the DMC Defendants’ opposition concluded: “The study shows that *Equisetum hyemale* can antagonize the hyperlipemia in rats.” *See Aldrich Aff.*, 2/9/06, Exhibit 1 (Binder 29, ch. *Equisetum Arvense*, Tab 4 (Xu 1993)).

Spearmint: Dr. Cassileth stated that there are no studies that support the use of spearmint for any of the aforementioned diseases. *See Cassileth Aff.*, FTC Summary Judgment Exhibit 27, attachment 3, page 3. However, a 2004 study concluded: “Collectively these findings suggest that spearmint tea protects against IQ and possibly other heterocyclic amines through inhibition of carcinogen activation and via direct effects on the activated metabolites.” *See Aldrich Aff.*, 2/9/06, Exhibit 1 (Binder 29, ch. *Mentha Spicata*, DBCT (Yu 2004)).

Spinach Dr. Cassileth stated that there are no studies that support the use of spinach for any of the aforementioned diseases. *See Cassileth Aff.*, FTC Summary Judgment Exhibit 27, attachment 3 page 3. However, a 1997 epidemiological study on over 12,000 people stated “These data do not allow us to distinguish among several potential explanations for the protective association observed between intake of carrots and spinach and the risk of breast cancer.” *See Aldrich Aff.*, 2/9/06, Exhibit 1 (Binder 30, ch. *Spinacea Oleracea*, Tab 1 (Longnecker 1997)). A more recent study concluded “Based on these results the glycolipids

fraction from spinach is potentially a source of food material for a novel anticancer activity.”

See Aldrich Aff., 2/9/06, Exhibit 1 (Binder 30, ch. Spinacea Oleracea, Tab 2 (Kuriyama 2005)). In regards to diabetes a 1995 study found that spinacea oleracea significantly “decreased the area under the glucose [glucose tolerance] curve and the hyperglycemic peak” in rabbits. *See* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 30, ch. Spinacea Oleracea, DBCT (Roman-Ramos 1995)).

Watercress Dr. Cassileth stated that “There are no studies that support the use of watercress for any of the aforementioned diseases”. Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 3. However a 2005 paper titled Broccoli and watercress suppress matrix metalloproteinase-9 activity and invasiveness of human MDA-MB-231 breast cancer cells stated “A high dietary intake of cruciferous vegetables has been associated with a reduction in numerous human pathologies particularly cancer”. *See* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 29, ch. Nasturium Officinale, Tab 3 (Rose 2005)).

White Willow Dr. Cassileth stated that “There are no studies that support the use of white willow for any of the aforementioned diseases. *See* Cassileth Aff., FTC Summary Judgment Exhibit 27, attachment 3, page 3. White willow is the natural source of Aspirin (*see* Aldrich Aff., 2/9/06, Exhibit 1 (Binder 29, ch. Salix Alba II, Tab 3 (Schmid 2001))) a drug prescribed for almost every type of pain. More pointedly a 2001 randomized double blind trial stated “It is concluded that the willow bark extract showed a moderate analgesic effect in osteoarthritis and appeared to be well tolerated.” *Id.* This study is yet another “a double blind , placebo controlled study,” which Dr. Cassileth alleges he was unable to find.

265. The DMC Defendants dispute that there is no scientific support for the health benefits of the ingredients found in Supreme Greens. Although the DMC Defendants relied

upon Guerrero to provide them with substantiation for his opinions about Supreme Greens during the period the infomercial featuring Guerrero was airing, they have subsequently gathered a significant amount of scientific data supporting the benefits of the ingredients in Supreme Greens. *See* Aldrich Aff., 2/9/06. Had the DMC Defendants known at the time that Guerrero had misled them about his qualifications and substantiation, they would have undertaken to gather this information at that time. In connection with all advertising currently run by the DMC Defendants, the featured speaker must provide all substantiation before the show is aired, which is reviewed by counsel and the company's scientific adviser. *Id.*; *see* Sciucco Aff., 6/9/05, Docket No. 86; Barrett Aff., 6/9/05, Docket 80. The DMC Defendants also seek independent verification of this data. Thus, although it appears that Guerrero may have misled many people about his qualifications, clinical training and substantiation, the DMC Defendants have adopted controls to assure that they are not subject to a similar problem in the future. *See* Barrett Aff., 2/10/06; Bernabei Aff., 1/25/06.

266.-268. The DMC Defendants dispute the FTC's selective submission of and citation to the PKF Report as the measure of "net" revenues to the DMC Defendants. That report also makes clear that the DMC Defendants suffered a net loss in connection with the Supreme Greens infomercial. *See* FTC Summary Judgment Exhibit 23. Because advertising promotions have significant up front costs and overhead, which are expected to be recovered over time, the FTC's request that the DMC Defendants cease running the Supreme Greens advertising in May 2004, which was agreed upon by the DMC Defendants, resulted in the loss of significant up front costs, as reflected in the PKF Report. *Id.*

269.-279. The DMC Defendants dispute the FTC's evidence concerning the autoship program. Contrary to the evidence submitted by the FTC, sales representatives were repeatedly

told to clearly state the terms of each purchase program, including any program that included future monthly deliveries. *See* Limbaugh Depo., 5/16/05 at p. 242, FTC Summary Judgment Exhibit 10; Mena Aff., 1/25/06. Because it is DMC's policy to provide all customers with a money-back guarantee on all products, and because a customer may cancel any purchase program at any time, it would not make any business sense to force a customer to sign up for a purchase program that was not clearly explained to them. *Id.*; *see* Radcliffe Aff., 6/6/04, Docket No. 14; Radcliffe Aff., 6/9/05, Docket No. 85; Barrett Aff., 2/10/06; Callahan Aff., 1/26/06. Doing so would simply result in the customer canceling the order, and DMC losing that customer's business in the future. Robert Maihos testified that it is the policy of DMC and ITV to always side with the customer and give them their money back unconditionally. *See* Maihos Depo., 7/20/05 at p. 203, FTC Summary Judgment Exhibit 8; Barrett Depo., 7/21/05, at p. 203, FTC Summary Judgment Exhibit 7. DMC strives to make customers happy with the sales process, which includes the ultimate decision to purchase products on any particular payment plan. The FTC's evidence concerning the autoship program is also belied by their own investigation. Specifically, in one of the "undercover" calls made to the DMC call center by FTC investigator Christina Turner, the sales representative specifically informed Ms. Turner of the various purchase plans and expressly told her that she was *not* being placed on autoship. Additionally, Ms. Turner submitted recorded calls which she agreed to be placed on an autoship program. The sales representative asked for her consent at which point she gave her express consent. *See* FTC's Motion to Modify June 23, 2004 Preliminary Injunction, May 31, 2005, Affidavit of Christina Turner Exhibit A, attachment 18 and attachment 17, Docket No. 71. While it is true that various commission structures provided incentives for sales representatives to encourage long-term purchase plans and continuity, such incentives were undermined if the

customer later cancelled their order because the plan was not clearly explained. Also, while it is true that repeat orders by customers are a significant source of revenue and a major part of running sales for consumable products, cancellations are a major distraction and expense, and must be avoided at all costs. Given DMC's money-back guarantee and open cancellation policy, which the FTC has never disputed exists, the FTC's theory and evidence regarding DMC's alleged practices in connection with its autoship program does not make sense, and it is disputed by the DMC Defendants. *See Ratcliffe Aff.*, 6/7/05, Docket No. 85; *Mena Aff.*, 1/25/06.

281.-283. The DMC Defendants dispute the FTC's evidence regarding the scripts provided to sales representatives concerning the autoship program. As noted above, all sales representatives were told to communicate clearly the terms of any purchase program to customers. Sales representatives were told to confirm that the customer consented to be placed on autoship, and DMC's policy has been and is to only place customers on autoship if they have consented. *See Mena Aff.*, 1/25/06; *Limbaugh Depo.*, 5/16/05 at p. 242, FTC Summary Judgment Exhibit 10.

284. The DMC Defendants dispute the FTC's contention that a customer's failure to object to future delivery of products upon being properly advised of the terms of the program is an improper sales practice. Specifically, while the FTC has termed this practice an "unauthorized autoship," it is in fact a "negative option" program, which has been routinely endorsed by the FTC as not violative of any law.² Under a "negative option" plan, it is perfectly appropriate under FTC guidance to provide a product to a customer with the proviso that the

² A negative option plan has been defined by the FTC as "an offer or agreement to sell or provide any goods or services, a provision under which, the customer's silence or failure to take affirmative action to reject the goods or services, or to cancel the agreement, is interpreted by the seller as an acceptance of the offer." *See* Part 310.2, Federal Register, dated January 29, 2003, at p. 4670. Thus, notwithstanding ITV's efforts to obtain verbal consent, it is clear that not all programs in which silence is the form of assent are deemed in violation of the FTC Act, or that the evidence cited by the FTC does not constitute a valid negative option program.

customer will be charged in the future for the product or plan in the absence of canceling the order. Thus, while the DMC Defendants dispute that they ever sought to purposefully place any customer on any plan without the customer's express consent, even had they done so as the FTC alleges, such practices would constitute no more than a negative option plan, which has been supported and endorsed by the FTC as appropriate. *See Mena Aff.*, 1/25/06.

285.-287. The DMC Defendants dispute the FTC's evidence regarding DMC's policies with regard to the autoship program. *See Ratcliffe Aff.*, 6/6/04, Docket No. 14; *Ratcliffe Aff.*, 6/9/05, Docket No. 85. DMC consistently sought to reduce the occurrence of customer complaints. *Id.* The minutes cited by the FTC do not reflect that Barrett acquiesced in the placing of customers on autoship without their consent, but exactly the opposite. The minutes of meetings and the testimony of the sales manager Simon Mena reflects that Barrett sought to reduce the number of customer complaints by instructing the sales staff that unauthorized autoships would not be tolerated. The FTC's citation to documents that reflect that Barrett was aware of customer complaints does nothing to demonstrate that this was a practice that was condoned, never mind encouraged, at DMC. To the contrary, the instances of customer complaints resulted in additional training and measures to record all customer calls, such that sales representatives could be monitored to assure that customer consent was obtained before any customer was charged for any product or program. *See Ratcliffe Aff.*, 6/7/05, Docket No. 85; *Mena Aff.*, 1/25/06.

288.-292. The DMC Defendants dispute the FTC's evidence regarding the scripts for Supreme Greens. All sales representatives were trained to confirm the terms of each and every sale with the customer and obtain their consent before charges were assessed. While sales scripts certainly encouraged the sales representative to promote a purchase plan that included reorders,

there is nothing in the scripts cited by the FTC that indicates that sales representatives were told or encouraged to place customers on the program without their consent. To the contrary, all sales representatives were told and trained to confirm the customer's consent before placing any charges on the customer's credit card. *See* Mena Aff., 1/25/06; Affidavit of Soraida Negron, June 6, 2005, ¶ 9, Docket No. 84; Affidavit of Matthew Ribaud, June 6, 2005, ¶ 18, Docket No. 79.

293.-304. The DMC Defendants dispute the FTC's evidence regarding the E8 promotion run by DMC for a short period during 2003. Specifically, the E8 program was designed as a program to provide a free product, E8 Daily, to customers, as an incentive for them to sign up to a reorder program for other products. The E8 program was designed as a "negative option" program, which has been endorsed by the FTC as an appropriate sales practice. Under the program, the customer was told that they would receive a free bottle of E8 Daily in exchange for signing up for the reorder program. Customers were told expressly that they would be charged for the program unless they canceled, and their consent was obtained to the entire program, including the free bottle and the reorder. *See* Barrett Depo., 7/21/05, at p. 199, FTC Summary Judgment Exhibit 7. However, DMC later learned that many customers saw the promotion as an easy opportunity to obtain a free product and then cancel, with no ramifications. In fact, many customers were encouraged by sales representatives to take advantage of DMC's offer by taking the product and then canceling. This manipulation of the program by customers was further exacerbated by the fact that DMC offered a slightly increased commission to sales representatives in connection with the program. As DMC became aware that sales representatives were encouraging customers to take the free product and cancel, DMC also learned that customers were being told to complain to customer service that the placement of

them on autoship was “unauthorized” or that they were incurring charges that they never agreed to. As the volume of calls increased and DMC realized that sales personnel were manipulating the program, the promotion was canceled. Overall, DMC lost money on the program and has not duplicated it, or any program like it, since 2003. *See Ratcliffe Aff.*, 6/9/05, Docket No. 85; *Mena Aff.*, 1/25/06; *Barrett Aff.*, 2/10/06.

305.-311. The DMC Defendants dispute the FTC’s evidence regarding unauthorized autoships and alleged changes to the sales and commission policies in early 2004. During this period, DMC implemented the Contract Genie, which recorded all calls between DMC salespeople and customers, and provided a mechanism that would confirm customer consent to the purchase of a product and the terms of the purchase. Because of this new system, DMC was better able to monitor the sales force and obtain evidence of unauthorized sales practices, which could then be disciplined appropriately. Prior to this time, it was difficult to confirm the exact conversation between the salesperson and the customer, and thus the company often could not confirm for certain inappropriate behavior. As is well known in the direct response industry, a substantial number of customers routinely have “buyer’s remorse” after making and confirming a purchase. These customers routinely call in to customer service to cancel their order, and although DMC always allows cancellations, the customer often feels the need to state that the purchase was somehow unauthorized. Customers also on occasion call their credit card companies to complain about a purchase even before calling customer service. Since implementing the Contract Genie, DMC has experienced a number of situations where a customer has called to complain about an unauthorized purchase, and the recording on the Contract Genie will confirm that the terms of the sale were fully communicated and the customer did clearly consent. Although the customer is free to cancel nonetheless, the Contract Genie has

shown that a number of customer complaints about alleged unauthorized charges are unfounded. Likewise, DMC has had a history of extremely low chargebacks from its merchant accounts, and extremely low risk. *See Callahan Aff.*, 1/26/06; *Ratcliffe Aff.*, 6/9/05, Docket No. 85. The DMC Defendants dispute that DMC's processing history had any influence on Chase Merchant Services increasing the reserve account. Rather, this increase was due to higher volume of transactions and the lack of a business history, i.e. that DMC was a young company and the industry in general. In addition, the DMC Defendants have been advised that Chase Merchant Services increased the reserve on DMC's merchant account because it was contacted by the FTC and disparaged by the FTC in its efforts to shut down DMC's business, not because of any issues with its chargeback rate or customer complaints. *See Maihos Depo.*, 6/20/05, at pp. 189, 192, Attachment 6, FTC Summary Judgment Exhibit 8. Based on the information communicated to it, DMC believes that the FTC investigators told the representatives of Chase that the FTC believed DMC was engaged in a practice of unauthorized autoships, notwithstanding its low chargeback rate. The claim of unauthorized autoships was then communicated back to DMC by Chase. DMC's chargeback rate remains one of the lowest in the industry. *See Ratcliffe Aff.*, 6/7/05, Docket No. 85; *Mena Aff.*, 1/25/06.

312.-318. The DMC Defendants dispute the FTC's evidence regarding the disciplinary actions taken against sales representatives for violations of company policy, including sales policies. Over the last several years, employees have been terminated for sales policy violations, including a failure to properly communicate the terms of a purchase to a customer or the terms of the autoship program. *See Barrett Depo.*, 7/21/05, at p. 195 FTC Summary Judgment Exhibit 7; *Maihos Depo.*, 4/7/05, at p. 174, FTC Summary Judgment Exhibit 9. The discipline handed out to any particular employee depends on the nature and egregiousness of the violation. While

Barrett stands behind his statement that intentional violations of the company's policies will lead to immediate termination, often the sales representative's violation is simply the product of inadequate training. In these cases, it is the policy to take the person off the sales floor, retrain them and give them a second chance. If it becomes clear that they cannot be trained, or cannot conform their conduct to the company's policies, they will be terminated. *See* Affidavit of Matthew Ribaud, June 6, 2005, Docket No. 79. As to the specific employee identified by the FTC, that employee has been terminated. However, before being terminated, the responsible sales manager did not believe the employee intended to mislead customers. Rather, as recognized in the documents submitted by the FTC, the salesperson's explanations were "unclear" and "confusing." When this is the case, as opposed to conduct that appears intentional, the salesperson is often given an opportunity to correct the problem before being terminated. *Id.* With over 200 sales representatives, there have been problems identified over time. When appropriate, these problems result in termination. Mena Aff., 1/25/06; Maihos Aff., 6/6/05, ¶ 24, Docket Nos. 82, 83; Barrett Aff., 6/7/05, ¶ 17, Docket No. 80; Negron Aff., 6/6/05, ¶ 9, Docket No. 84.

319.-329. The DMC Defendants dispute and object to all of the evidence submitted by the FTC in connection with its review of the DMC customer database. In connection with this information, the FTC has submitted the affidavit of Stefano Sciolli, a program analyst with the FTC. Mr. Sciolli was never identified as an expert witness in this case, and he is otherwise not competent to testify. Mr. Sciolli was never identified as a witness at all, despite a specific discovery request for all information upon which the FTC would be relying at trial. Thus, the DMC Defendants have had no opportunity to depose Mr. Sciolli, or to cross-examine his methods in reviewing the DMC customer database. Moreover, the DMC Defendants dispute Mr.

Sciolli's analysis on its merits. Among other things, Mr. Sciolli uses an analysis based upon "unique customers" and "unique relevant customers" that is vague and incompetent, and cannot form the basis of any conclusions about the customer database or the information on that database. Moreover, Mr. Sciolli and the FTC both acknowledge and recognize that the records are not complete, may have significant and material human errors and could reflect incorrect or misentered data regarding the very issues that the FTC seeks to admit in connection with its summary judgment motion. For example, Brian Middendorf, the creator of the database, testified that the information is necessarily incomplete, and that the customer representatives often entered incomplete or inaccurate data. Thus, the conclusions reached by Mr. Sciolli are meaningless and leave many issues of fact regarding the number of customer complaints on any particular issue, including alleged unauthorized autoships. Finally, the only relevant figures cited by Mr. Sciolli that have any bearing on the issues discussed by the FTC are the following: (1) that DMC has 1,149,796 customer records, and (2) only 8,213 of those customer records apparently reference unauthorized autoships. Based on these figures submitted by the FTC and confirmed by Mr. Sciolli, *less than one percent (1%)* of all of DMC's customers complained about an occurrence of unauthorized autoship. Moreover, given the implementation of the Contract Genie and the increased oversight of the sales floor, these occurrences are now a fraction of that small amount. Finally, Mr. Middendorf admits he never worked in sales or in customer service and could not state for certain what any particular sales representative understood any particular data entry to indicate. *See* Declaration of Stefano Sciolli, dated December 13, 2005, FTC Summary Judgment Exhibit 31; Middendorf Depo., 1/6/05, at p. 108, FTC Summary Judgment Exhibit 31, Attachment 2.

330.-335. The DMC Defendants object to the submission of Ms. Turner's undercover call as evidence of any DMC sales pattern or practice, and dispute that it is representative of the typical DMC sales call. To the contrary, in connection with its motion to modify the injunction in this case, the FTC submitted several, but not all, of the transcripts it had created in connection with calls to the DMC sales staff. *See* Robertson Aff., 9/20/05, Docket No. 112. The FTC then implied that these selective transcripts were somehow representative of the typical sales call. *Id.* In response, the DMC Defendants obtained a number of additional transcripts, which demonstrated that the majority of calls that the FTC had recorded were handled properly by the sales staff, and that the terms of each purchase program were properly and fully communicated. *Id.* Acknowledging that it had made additional calls other than those identified to the court and the DMC Defendants, and acknowledging its failure to produce all of the transcripts, combined with the substance of those transcripts demonstrating that many calls were properly handled, the FTC agreed to withdraw any argument on its claim of continued inappropriate sales practices in connection with its pending motion. *See* Transcript of Hearing, dated October 14, 2005, Docket No. 136. For the same reason as previously, the DMC Defendants dispute the FTC's "evidence" of the undercover calls made by Ms. Turner as incompetent, especially as a means to establish a pattern of inappropriate sales practices either historically or presently. *See* Motion to Continue Hearing and for Sanctions, and Supporting Memorandum of Law, dated September 20, 2005, Docket Nos. 110, 111.

336.-344. The DMC Defendants dispute the FTC's evidence regarding other programs, none of which are the subject of the present action and none of which have been formally challenged by the FTC. To the extent that the FTC contends that these shows are somehow representative of shows produced by DMC, the evidence is to the contrary. For example, as set

forth in Donald Barrett's June 9, 2004 affidavit submitted to the Court, the UroCaps advertisement was not produced by DMC, but was produced and owned by Ideal Health. Likewise, no advertising was ever produced by DMC for the 7-Day Miracle Cleanse. *See* Barrett Aff., 6/9/04, Docket No. 25. Finally, as set forth in prior affidavits submitted by Mr. Barrett to the Court, DMC never sold any product in connection with the advertising for the Stress Shield. *Id.*; Barrett Aff., 6/23/04, Docket No. 31. In addition, DMC has produced many other programs for non-dietary supplement products, such as books, home products, and electronics. *See* Barrett Aff., 2/10/06.

345.-347. As set forth more fully in its opposition to the FTC's motion to modify the Court's preliminary injunction, the DMC Defendants dispute the FTC's evidence regarding Mr. Barrett's intentions at the time he submitted an affidavit to this Court in connection with the FTC's original motion for a preliminary injunction. *See* Memorandum in Opposition to Motion to Modify June 23, 2004 Preliminary Injunction, dated June 9, 2005, Docket No. 89. With respect to the affidavit previously submitted by Barrett in June 2004 regarding the business decision not to produce infomercials for ingestible products, he has testified that that was a true and accurate statement at the time he submitted that affidavit. *See* Barrett Aff., 6/7/05, Docket No. 80. As of June 2004, Barrett has testified that he had made the decision to stop running infomercials for ingestible products, because he was unable to determine the standard applied by the FTC for competent and reliable scientific evidence in connection with those products, and because he did not believe any of the product proposals that we had seen at that time had sufficient substantiation to meet the FTC's requirements. *Id.* Consistent with his decision to move the company away from infomercials for ingestible products, he testified that between early June of 2004 and June 2005, ITV produced and/or aired no less than fifteen infomercials

for non-ingestible products. *See* Barrett Aff., 6/7/05, ¶¶ 5,6, Docket No. 80. Barrett also testified that the longest running infomercial produced by ITV between June 2004 and June 2005 was not for an ingestible product. Rather, this infomercial, featuring a medical doctor, provided advice on healthy living and eating well, with references to the benefits of believing in God and nature. *Id.* at 7. Other than requesting an additional disclaimer, the FTC did not raise any additional questions or issues with that show. During 2004, DMC was also in the process of producing an infomercial for an air purifier for a major multi-national corporation, but because of the FTC's press release concerning this case, the company backed out at the last minute. Similarly, DMC has been in discussions with large and small companies in electronics, financial services, real estate and other non-health industries regarding producing infomercials. In many cases, the pendency of the FTC action and the FTC's press releases regarding ITV have negatively impacted these negotiations. *Id.* at 8.

348. The DMC Defendants dispute the FTC's evidence in connection with the Sea Vegg, Dr. Day, RegenaLife and Flex Protex advertising. In the case of each of these advertisements, the DMC Defendants possessed a reasonable belief that the opinions expressed in the advertising were supported by competent and reliable scientific evidence, which has been previously submitted to the Court in connection with the FTC's previously filed motion for modification of the existing preliminary injunction order. *See* Sciucco Aff., 9/25/05, Docket No. 120. The DMC Defendants also added many disclaimers in these shows to meet the Court's prior injunctive order, and the FTC has never argued that the disclaimers were not compliant with the Court's prior order or otherwise inadequate. *See* Goljan Aff., 6/6/05, Docket No. 90. The FTC also has never brought any action, either in court or administratively, in connection with these shows. The DMC Defendants' dispute the FTC's contention that these shows

somehow demonstrate a continuing course of unlawful conduct. To the contrary, based upon the efforts to obtain and review substantiation for these shows, as well as having the shows reviewed by counsel, these shows demonstrate the efforts that the DMC Defendants have undertaken to meet their compliance obligations. *See Sciucco Aff.*, 9/25/05, Docket No. 120.

349.-354. The DMC Defendants dispute the FTC's evidence in connection with the Renuva infomercial. As set forth in detail in their opposition to the FTC's motion to modify the injunction previously entered by the Court, which is incorporated herein in its entirety, the DMC Defendants did not produce this infomercial and had no input into its contents or format. Rather, ITV was initially approached by the producers of the infomercial who inquired whether ITV would be willing to answer phones for the infomercial and process customer orders. *See Barrett Aff.*, 6/7/05, ¶¶ 16,17, Docket No. 80. After reviewing the infomercial, and prior to answering the telephones, ITV's in-house legal and compliance staff raised a number of questions with the producers of the show, questioning the substantiation for the claims in the show. In response, the producers provided substantial documentation to ITV, which was reviewed. *Id.* at ¶ 17. The producers also informed ITV that they had requested a Washington, D.C. law firm with expertise in FTC compliance to review the show. Based upon these representations and ITV's limited involvement in connection with the show, ITV agreed to proceed. *Id.*; *Sciucco Aff.*, 9/25/05, Docket No. 120. Later, ITV expanded its relationship with the producers of the show and took a more active role in distribution. At all times, ITV believed that there was a wealth of competent and reliable scientific evidence for the claims in the Renuva show. ITV has also submitted supporting affidavits from experts, including a medical doctor and a Ph.D., as well as numerous scientific studies and data, to support the claims in the show. *See Affidavit of Frank Greenway, M.D.*, Docket No. 75. As set forth in these expert affidavits, the DMC Defendants dispute the

conclusions and opinions of Dr. Vance, submitted by and relied upon by the FTC. In addition, ITV has been informed that the producers of the Renuva show have since completed a short-term pilot study that supports the claims in the show. Nonetheless, ITV no longer has any association with the Renuva show. *See Sciucco Aff.*, 9/25/05, Docket No. 120.

355. As set forth in the DMC Defendants' opposition to the FTC's motion to amend the preliminary injunction, a significant amount of scientific literature and studies exist that support the opinions expressed in the RegenaLife advertising. *See Sciucco Aff.*, 9/25/05, Exhibits 19-20, Docket No. 120. These studies and literature, which were submitted to the Court in connection with the prior opposition, are incorporated herein by reference in their entirety. As these materials demonstrate, the DMC Defendants, in conjunction with their in-house attorney and their scientific adviser, undertake significant efforts to assure that the opinions expressed in the advertising are reasonable and have scientific support. *Id.* The FTC has put forth no evidence to refute the evidence and support gathered by the DMC Defendants in connection with the RegenaLife advertising. *See Memorandum in Opposition to Motion to Modify June 23, 2004 Preliminary Injunction*, dated June 9, 2005, Docket No. 89.

356.-360. The DMC Defendants dispute the FTC's evidence in connection with the Sea Vegg advertisement. As set forth in detail in their opposition to the FTC's motion to modify the injunction previously entered by the Court, which is incorporated herein in its entirety, the DMC Defendants obtained reasonable substantiation for the opinions expressed in the Sea Vegg advertisement prior to its airing. *See Memorandum in Opposition to Motion to Modify June 23, 2004 Preliminary Injunction*, Docket No. 89. This substantiation has been confirmed by the opinions of four separate scientific experts, whose opinions previously have been submitted to the Court and are incorporated by reference herein. *Id.*; *Maggs Aff.*, Docket No. 76; *Teas Aff.*,

Docket No. 91; Myslabodski Aff., Docket No. 121; Kraan Aff., Docket No. 122. These experts directly refute the testimony of Christine Skibola submitted by the FTC as its scientific expert.

Id. Moreover, certain aspects of Dr. Skibola's testimony support, rather than refute, the conclusions of the DMC Defendants' experts. As demonstrated by the evidence submitted by the DMC Defendants, numerous issues of fact exist regarding the scientific substantiation for the opinions expressed in the Sea Vegg advertisement, and these issues cannot be resolved in a summary proceeding or on a motion summary judgment. *Id.*

361.-362. The DMC Defendants dispute the FTC's evidence in connection with the Flex Protex advertisement. As set forth in detail in their opposition to the FTC's motion to modify the injunction previously entered by the Court, which is incorporated herein in its entirety, the DMC Defendants obtained reasonable substantiation for the opinions expressed in the Flex Protex advertisement prior to its airing. Flex Protex is a patented natural Cox-2 inhibitor developed by a publicly traded company, NutraCea. NutraCea spent millions of dollars on research and development of the product and has two Ph.D. research scientists on staff that developed the product and provided substantiation for the product. *See* Barrett Aff., 2/10/06. In addition, the DMC Defendants sought and obtained the opinion of a scientific expert, Michael Glade, Ph.D., in support of the opinions expressed in the advertisement, which previously has been submitted to the Court and is incorporated by reference. *See* Robertson Aff., 10/13/05, Attachments A and B, Docket No 124; Aldrich Aff., 9/28/05, Attachment A, Docket No. 118. Additional evidence in support of the product and the advertisement have been submitted to the Court. *Id.* That evidence is incorporated herein and establishes that there are numerous issues of fact in connection with the Flex Protex advertisement.

363.-366. The DMC Defendants dispute the FTC's evidence regarding the ERSP and the circumstances surrounding the referral of the Renuva and Sea Vegg advertisements to the FTC. As set forth in detail in its opposition to the FTC's motion to amend the Court's preliminary injunction, which opposition is incorporated by reference, the ERSP was unequipped and unwilling to review the volume of detailed scientific substantiation provided by the DMC Defendants to the ERSP. *See Sciucco Aff.*, 9/28/05, Docket No. 120. Specifically, during ITV's participation in the ERSP process, it became clear that the ERSP is an organization which employs only one attorney, Peter Marinello, who reviews all advertising in the ERSP, amounting to thousands of advertisements. *Id.* This one individual has been given sole discretion and authority to determine whether such advertising meets his subjective analysis of what "he" personally thinks is proper and scientifically substantiated. Mr. Marinello, however, has admitted that he does not have a scientific background, and made comments that demonstrated that he did not read – or understand – the scientific studies provided by ITV. *Id.* Moreover, because of his apparent lack of interest in the actual scientific support for Renuva, Mr. Marinello never provided ITV the opportunity to discuss with him the pilot study on the ingredients of Renuva conducted in 2005.³ That study clearly demonstrates with statistically significant evidence the claims made in the advertising for Renuva. The overall ERSP process is fundamentally flawed, particularly in connection with reviewing scientific studies and evidence submitted to the ERSP. Critically, there is no appeal process, there is no scientist or medical expert on staff, and the ERSP guidelines are ambiguous and vague concerning the standard of substantiation applied by Mr. Marinello. *Id.* Nonetheless, ITV forwarded ERSP thousands of pages of documentation, including scientific journals and studies, and similar scientific

³ Because the pilot study was provided to DMC only upon condition of strict confidentiality, it has not been provided to the Court.

information, in support of the Renuva and Sea Vegg advertising, and also made certain modifications to the advertising to address issues raised by Mr. Marinello. Notwithstanding these efforts, in ITV's view Mr. Marinello had concluded that no edits would be sufficient to satisfy him, and he had determined that the only solution was to prohibit altogether the airing of the show, in any form. Compounding the problems with the ERSP process, the ERSP violated its own confidentiality policies and issued false press releases regarding ITV and DMC. *See Sciucco Aff.*, 9/28/05, Docket No. 120. Because of these ongoing disagreements, ITV has since filed suit against the ERSP in Massachusetts Superior Court, and ITV's membership in the ERSP has been terminated. *See ITV Direct, Inc. v. The Electronic Retailing Assn., et al.*, Case No. CV 2005-02139 (Mass. Super. Ct. Essex Co. Dec. 12, 2005).

367. The DMC Defendants dispute the amount of money that the FTC claims was sent by Triad to DMC, Direct Fulfillment, Inc., Barrett and BP Marketing. No accounting was ever provided by Triad to DMC, despite repeated requests. *See Barrett Depo.*, 7/21/05, at pp. 40-41, FTC Summary Judgment Exhibit 7. Moreover, in connection with other litigation filed by third parties against DMC, it has become apparent that Triad often credited payments to DMC or other entities despite never actually sending any funds. For example, Triad would credit payments to DMC when it would purchase product from third parties, yet no money would ever actually be sent to DMC. Thus, the amount of money actually sent to DMC and the other entities is not clear. *See Barrett Depo.*, 12/22/03, at pp. 86-87, FTC Summary Judgment Exhibit 6; *Barrett Aff.*, 2/10/06.

372.-374. The DMC Defendants dispute the use and transfer of funds sent by Triad to Barrett's personal bank account. As Barrett testified, these funds were properly accounted for as funds sent to DMC, but they were sent directly to Barrett in connection with payments that were

due in the short term on his house. *See* Barrett Depo., 7/21/05, p. 251, FTC Summary Judgment Exhibit 7. Barrett admits that some of these funds were used for construction of his house, but disputes the amount and that all of the funds were used for that purpose. *Id.* Some of these funds were put back into the business of DMC, and were used to pay salaries, overhead and other expenses in connection with the business. *See* Barrett Aff., 2/10/06.

379.-383. The DMC Defendants dispute the FTC's evidence regarding payments to BP Marketing and the services performed by BP Marketing. As Barrett testified, BP Marketing was owned by Steve Paris, and was established to organize and conduct business with third party distributors. *See* Barrett Depo., 7/21/05, at pp. 40-41, FTC Summary Judgment Exhibit 7. BP, working directly with Triad, would solicit distributors to sell the coral calcium product and would organize deliveries of product and the retention of King Media to purchase media time. *Id.*; Stern Depo., 7/15/05, at pp. 134-36, 171-72, FTC Summary Judgment Exhibit 15. Payments made to BP Marketing by Triad were made in connection with this relationship and represented commissions on product purchased from Triad and media purchased from King Media, among other services provided by Triad to distributors. *See* Barrett Depo., 7/21/05, pp. 26-27, FTC Summary Judgment Exhibit 7; Barrett Aff., 2/10/06; Stern Depo., 7/15/05, at pp. 171-72, FTC Summary Judgment Exhibit 15.

Respectfully submitted,

Dated: February 10, 2006

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